8th Annual

COOLCHAIN EUROPE 2009

January 27-30 2009

Sheraton Airport Hotel, Brussels, Belgium

IQPC International Quality & Productivity Centre

pharma IQ a division of IQPC

- Drive efficiency and compliance into your cool chain distribution, storage and transport by implementing solid long-term process improvements
- Assess cost-effective and environmentally aware logistical options, using industry perspectives on alternative modes of transport – sea, rail, air and ground
- Reduce human error and temperature deviations by developing a more robust quality system including additional training and effective master quality agreements
- Ensure all your international cool chains – bulk, IMPs and finished products – are delivered on-time and safely by overcoming custom challenges in emerging markets and implementing innovative logistic strategies
- Guarantee product integrity to the 'Last Miles' by implementing downstream compliance programmes, new technology and improved communications

The end of failed shipments?

"I enjoy coming to Brussels every year to meet colleagues and cross check what we're doing."
Pfizer

Attend the industry's favorite cold chain event to learn from 35+ top thinkers, including:


Chairperson **Dr. Rafik H. Bishara**, Technical Advisor and Chair Pharmaceutical Cold Chain Interest Group (PCCIG) USA Branch, **PDA**


David A. Ulrich, QA Distribution Director, Global Pharmaceutical Operations (GPO), Strategic Quality Initiatives (SQI), **Abbott Laboratories**


Dr. Peter Kulmburg, Head of Global Quality Assurance TR&D, **F. Hoffmann - La Roche AG**


Michael Schmitz, Compliance and Facilitation Policy, **World Customs Organisation**


Ingo Ocklenburg, Global Sourcing Manager, Distribution Logistics, **Bayer Healthcare**


Richard Peck, Cold Chain Technology Lead, **Wyeth**


Pier Pollini, Director of Supply Chain Execution, **Baxter Healthcare**


Gert-Jan Van Diest, Cold Chain Manager, Logistics, **Abbott**


Tom Bolger, Logistics Specialist, **Genzyme**


Nigel Bleakley, Validation Engineer, **UCB Celltech**


Dr. Michel Zaffran, Senior Advisor, **World Health Organisation** & Director of Project **Optimize**

www.coolchaineurope.com

0800 652 2363 or +44 (0)20 7368 9300 | +44 (0)20 7368 9301 | enquire@iqpc.co.uk | www.coolchaineurope.com

Welcome

"Refreshing ideas on cold chain.
Janssen Pharmaceutica

"Best seen yet. Very valuable.
Genzyme Ireland

"There is definitely some things I can use and can take back with me.
H. Lundbeck A/S

"Very valuable: great platform to exchange information and thoughts to vendors and business colleagues.
Amgen

Dear Colleague,

Cost reduction pressures, in particular rising fuel costs, have had a significant impact on temperature controlled logistics and supply chains in the pharmaceutical industry. This has led to manufacturers evaluating alternative modes of transport, including rail, sea and ground for cool chain distribution.

At Cool Chain Europe 2009, you will compare new quality initiatives, transportation strategies and qualified packaging which offers more control, increased compliance and efficiency for international distribution of cool chain products, IMPs and bulk material.

In its 8th year, CCE Brussels is the original annual gathering of 'who's who' in the cool chain. Just ask a colleague! It's your best way to get up-to-speed with industry best practices in cool chain management.

New for Cool Chain Europe 2009:

- Pre-Conference Seminar: Assessing Opportunities and Overcoming Challenges in New Markets, China, India and Africa
- Keynote Dinner Motivational Speaker: Michel Zaffran, Head of the Optimize Project, World Health Organisation
- 18 New Case Studies: Including "Last Miles" Distribution, Master Quality Agreements, Sea Transportation, Fine Arts, Outsourcing, Human Plasma Transport, Kaizen Cool Chain and more…!
- 6 New Pre-Conference Specialist Discussion Forums:
  - A) Dangerous Goods and Hazardous Materials International Regulations
  - B) Considerations for Transporting Temperature Sensitive Pharmaceuticals
  - C) How to Hold your Partners to High Quality Operational Standards
  - D) Building Strong Post-Qualification Partnerships
  - E) Innovative Distribution Solutions for Global Clinical Supplies
  - F) Reusable and Recyclable Packaging
- New Focused Tracks on Cool Chain Operational Process Improvements and International Cool Chains
- New Cool Chain Europe Excellence Award Category, Best Service Provider of the Year 2009, presented during the Gala Dinner

Table of Contents

"I enjoy coming to Brussels every year to meet colleagues and cross check what we're doing."
Pfizer

"I have enjoyed this event and found it very interesting to listen to other pharma companies experiencing the same challenges with cool chain.
UCB Celltech

> Exchange, communication, networking, and awareness are key and have been greatly facilitated by this conference.
> Agilent

We know it's not always easy to take the time out the office away from your busy schedules and commitments, but from talking with many of you, we know January in Brussels is the place to get up-to-speed and informed on the latest practice being implemented by your colleagues in other organistations.

That's why, for CCE 2009, we're working hard to once again bring you innovative discussion topics, fresh new case studies by multi-nationals, as well as SME's, and additional networking opportunities over the four day event.

We look forward to seeing you in January in Brussels for the 8th annual Cool Chain Europe forum.

Sincerely,

The Cool Chain Europe Advisory Council

> Very valuable. Many new technical cold chain solutions have been presented. A few of them are important enough to take immediate action in order to test them!
> Nederlands Vaccin Institunt

Courtney Becker-James
Event Director
Cool Chain Europe
Pharma IQ

Dr. Rafik H. Bishara
Technical Advisor
Chair, Pharmaceutical Cold Chain Interest Group (PCCIG) USA Branch, PDA
Cool Chain Europe 2009 Chairperson and Advisor

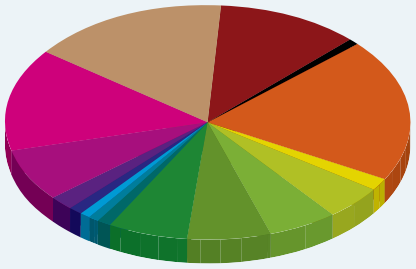
Els Pasmooij
Business Leader, Cold Chain Operational Excellence
Amgen
Cool Chain Europe 2009 Advisor

Henry Ames
Director of Strategic Marketing
Sensitech
Cool Chain Europe 2009 Advisor

Paul Condon
Director of Materials
Genzyme
Cool Chain Europe 2009 Advisor

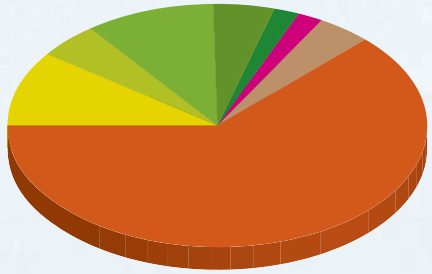
Joachim Kuhn
Physicist, CEO and Co-Founder
va-Q-tec AG
Cool Chain Europe 2009 Advisor

300+ cool chain professionals attending are from:



Austria	1%	Lithuania	1%
Belgium	21%	Monaco	1%
Croatia	2%	Slovenia	1%
Denmark	5%	Sweden	2%
France	6%	Switzerland	8%
Germany	7%	The Netherlands	15%
Ireland	7%	United Kingdom	17%
Israel	1%	United States	12%

Industry



Biopharmaceutical Manufacturers	64%
3PLs, Logistic Partners	10%
Freight Forwarders	5%
Packaging Partners	10%
Medical Device, Diagnostic Manufacturers	5%
Blood Banks	2%
Wholesalers	2%
Regulatory, Government Authorities	4%

COOL CHAIN EUROPE 2009

Conference Day One
Wednesday 28 January 2009

8.00 **Registration and Morning Coffee**

8.45 **Pharma IQ Welcome**

8.50 **Opening remarks from Conference Chair Dr. Rafik H. Bishara,** Technical Advisor and Chair of Pharmaceutical Cold Chain Interest Group **(PCCIG)** USA Branch, **PDA**

9.00 **Understanding and Complying with MHRA Guidelines**
- Shipping according to label claim: The regulatory position on variances and mixed shipments
- What if there is no stability data?
- Temperature deviations: Practical considerations and staying in compliance
- Where do regulators stand on energy efficiency measures?

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

09.45 **Aligning Cool Chain Initiatives Across Industry and Partners**
- New initiatives by the PCCIG: Including 'Last Miles' Task Force
- Highlighting some feedback to elements of Technical Report 39 that requires clarification
- Underlining the importance of partnerships to ensure effective, world-wide cool chain operations
- QA developments in the Cool Chain: In an effort to work towards developing more robust quality management systems

Dr. Rafik H. Bishara, Technical Advisor and Chair Pharmaceutical Cold Chain Interest Group (PCCIG) USA Branch, **PDA**

10.30 **Morning Refreshments and Networking Break**

11.00 **Developing a Master Quality Agreement for Cool Chain Partners: Setting and Communicating Expectations**
- ICH Q10 interpretation and inclusion into cool chain partner agreements
- Defining the responsibilities and communication processes for quality related activities of suppliers
- Streamlining quality agreements across transportation partners
- Developing quality agreement templates for qualification of supply chain partners
- Minimising human error and risks with several handovers by establishing an effective quality programme with updated contractual agreements
- Outlining necessary and useful KPIs in an effective quality agreement
- Measuring KPIs and putting a value on each (weighted/tiered approach)
- Tracking and communicating KPIs and keeping partners accountable (quality business reviews, QBRs)
- Monitoring incoming materials to ensure quality operations

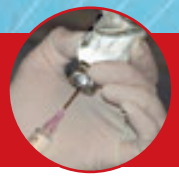
David A Ulrich, QA Distribution Director, Global Pharmaceutical Operations (GPO), Strategic Quality Initiatives (SQI), **Abbott Laboratories**

11.45 **Panel Discussion: 'Ask the Regulator' How to Interpret and Implement European Regulations on Cold Chain Transport of Biopharmaceuticals**
(Anonymous questions may be submitted to the panel beforehand by sending to courtney.becker@iqpc.co.uk)
- How are companies justifying their actions and validation plans to regulators?
- Regulators advise they want to see more control over the cold chain – but what exactly will demonstrate this?

All morning speakers and participants are invited to join the discussion

12.45 **Networking Lunch**

Track A
Cool Investigational Medicinal Products

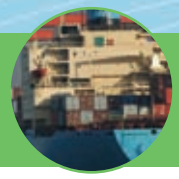


14.00 **Development of Cold Chain Containers for Investigational Medicinal Products**
- Evaluating business needs to transporting cold clinical supplies
- NOEX vs. ALEX: a no excursion container vs. a container that allows minor deviations
- Evaluating cost, efficiency and sophistication of containers for IMPs: Two-To-Eight (TTE) and the Courier Cold Shipper (CCS)
- Problems encountered in practical use of containers
- Estimating costs vs. value and efficiency of cold chain packaging

Dr Peter Kulmburg, Head of Global Quality Assurance TR&D, **F. Hoffmann La Roche AG**

14.40 **Cold Chain Distribution of Clinical Supplies Case Study: Efficient Distribution Supplies Around the Globe**

Track B
Cool Chain Logistics and Transportation



14.00 **Human Plasma Case Study: Transportation and Validation via Land, Sea and Air**
- Fundamentals of transport validation is transport equal to mobile storage?
- Comparison between airfreight (short passive cooled transports) vs. sea freight (long active cooled transports)
- Weaknesses and strengths of systems and advantages and disadvantages of certain methods
- Transportation monitoring, validation or both?
- Monitoring positions from integrated sensors and product storage places
- Interpretation of recorded data
- Handling error / failures or off-limit conditions

Oliver Gross, QA Manager, **ZLB Plasma**

14.40 **Optimising Cold Chain Logistics by Implementing Cost-Containment and Environmental Improvements**

- Identifying weaknesses and gaps in clinical supply chain
  - Improving stability studies and gathering enough data to ensure process improvements
  - Managing excursions for clinical distributions
  - Implementing quality control standards for each distribution link

Franco Pasquale, Senior Manager of Manufacturing Collaborations, **Genentech**
Rognvald Lamb, EMEA Logistics Manager**, Fisher Clinical Services**

15.20 Developing Sufficient Stability Data to Maximise Label Conditions for Shipping and Storage of Clinical Materials

- Merging stability guidelines to streamline world wide quality initiatives
- Making stability information available worldwide to scientists
- Using stability data to maximise label conditions to allow for optimal temperature excursions

All participants of this afternoon are invited to join this discussion

16.00 Networking Break

- Maximising transportation volume per shipment to get a "green" result
- Choosing the right security level and risk assessments
- Evaluating if a 're-usable' packaging concept works in your logistics strategy
- How to re-write and check your specifications
- Is your logistics management ready to progress and follow the evolution year by year?

Gilles Labranque, Chairman and Managing Director**, Sofrigam**

15.20 Improving Transportation Processes and Product Integrity with 3PL Partners

- Identifying weak links in the distribution process measured by temperature deviations
- Educating Freight Forwarders, Airlines and 3PLs on GXP cold chain practices
- Defining, communicating and implementing shipping guidelines and working procedures
- Measuring the performance of 3PLs to effectively monitor temperatures and reduce human error
- Lessons learned in how to improve relationships and the outcome with transportation partners

Jim Bacon, Director, Global Demand Planning and Customer Operations, **Talecris Biotherapeutics**

16.00 Networking Break

Roundtable Discussions

16.30
After a full day of presentations, it's time for all participants to take an active role and get answers to specific questions. These informal discussions will provide an opportunity to exchange ideas related specifically to job functions and interests. Facilitators will present a short case study as an introduction to the 60 minute discussion and question session.

A Modern Modes of Cold Chain Transport: Weighing Cost, Compliance, Control and Capabilities

B Security Challenges and Tools for the Cool Chain

C Weighing Cost/Benefit vs. Value of Green Packaging Solutions and Strategies for your Cold Chain

D Investing in Training and Building a Skill-based Work Force to Decrease Turnover and Failed Shipments

E Shipping 'Living' Biological Materials with Cryogenic Technology and Implementing Speciality Logistics for Large Molecule Drugs

F Understanding What Temperature Excursions are Allowable and Where to Put in the Regulatory File

G Improving Airline Logistics and Controlling Temperatures in the Air: IATA Developments

H Ambient Shipping Justification and Requirements vs. ICH Stability

I Ensuring Product Integrity Through to the "Last Miles" of the Cool Chain

J Cold Medical Devices: Assessing Packaging Limitations and Transportation Solutions

17.30 Summary of Roundtable Discussions

18.15 Closing Remarks from Chairperson

18.20

Networking Drinks Reception

19.30

Cool Chain Europe Dinner and Excellence Awards

To recognise a colleague's achievements, go to **www.coolchaineurope.com** to nominate a colleague for one of the CCE Awards:

- Most Influential Team, Person, Organisation or Project
- Top Technology Provider of the Year
- Best Service Provider of the Year

Dinner Keynote Address

20.00 Overcoming Current and Future Challenges Getting Vaccines to Remote Populations: Why the Cold Chain Matters So Much

- Statistics on improved healthcare: Why the cold chain matters
- Describing the challenges of the last miles of the vaccines supply chain today and in the coming years
- Defining the technology, systems and ingenuity needed to get life-saving vaccines to remote populations
- Working together to make a difference and utilising collaborations with Ministries of Health, WHO and NGO's
- How pharmaceutical manufacturers can help

Dr. Michel Zaffran, Senior Advisor**, World Health Organization and Director of Project Optimize**

Conference Day Two
Thursday 29 January 2009

8.00 Morning Coffee

8.45 Chair's Opening Remarks

Global Markets: International Cool Chains

8.50 **Keynote Session:**
WCO Initiatives to Improve Security and Trade Facilitation in Today's Global Pharmaceutical Market
- Explaining the revised Kyoto convention and what key pharmaceutical markets such as India and China have agreed to
- Developing unified and transparent customs procedures for industry to have one point of contact at the WCO, who then coordinates with FDA
- SAFE Framework – Establishing a set of standards to provide supply chain security and facilitation at a global level to promote certainty and predictability
- Promoting customs reform and modernisation IPR enforcement in new pharmaceutical markets

Michael Schmitz, Compliance and Facilitation Policy, **World Customs Organisation**

9.30 **Assessing Airlines for Trusted Handling of Pharmaceuticals Internationally and Implementing Effective Temperature Controlled Processes**
- Key challenges and examples of how temperature deviations still occur on airlines
- Getting a grip with 0-25°C ambient temperatures on airlines: Describing the ideal solution
- Gaining more insight into how airlines in international hubs such as Dubai handle and treat our products
- Discussing label requirements for temperature sensitive medicinal freight
- Understanding the difference in opinions between airport authorities and airlines with regards to 'speciality products' and how they should be handled

Ingo Ocklenburg, Global Sourcing Manager, Distribution Logistics, **Bayer Healthcare**

10.10 **Cold Chain Packaging Carbon Footprint: Commercial Strategies for Reduction**
- Dispelling environmental myths and clarifying terms
- Life Cycle analysis methodology and tools for cold chain packaging
- Evaluating biodegradable packaging options for cold chain packaging
- Application of the 4R's to temperature control packaging
- Sustainable supply chain strategies
- Comparing approaches of different companies: what actions are being taken now?

David Walsh, CEO, **DGP Group**

10.50 Networking Break

11.20 **Systems Applied to Ensure the Traceability of Products all the way to the Patient**
- Challenges in achieving true visibility of temperature controlled products
- How to gain transparency and control of the supply chain through new technologies
- Localised country solutions featuring Germany with RFID and the UK 's unique satellite tracking system

Jason Johnson, European Key Account Manager, **Movianto Group**

11.35 **Best Practice Transportation of Temperature-Sensitive Pharmaceuticals**
Quality and consistency in transportation and temperature control, is significantly enhanced through the effective use of end-to-end custodial control, en-route monitoring and a capability for timely and effective contingency intervention. Effective pre shipment planning, including a mutual discussion of solution options between carrier and shipper, can significantly enhance quality and economy for pharmaceutical shippers.

- Pre-assessment and shipment planning
- En-route monitoring
- Contingency planning
- Evaluation of carriers' quality systems
- Communication: Establishing an effective Transportation Quality Agreement

Tom Bolger, Logistics Specialist, **Genzyme**
Jeff Sitzlar, Manager, Business Development, **FedEx Custom Critical**

Panel Discussion:
12.15 **Sea Transport of Pharmaceutical Products: Exploring the Options and Defining Ways to Work Together**
- Examining current reefers on the market that afford cost-effective, low risk options for transporting pharmaceutical products
- Discussing risks of sea transport: longer routes, port authorities and various other handlers
- Defining how to overcome these key concerns in maintaining temperatures long-term via sea
- Comparing efficiency of sea transport
- Lessons learned in first shipments via sea

Panelists:
Henry Ames, Strategic Marketing Director, **Sensitech**
Jens Lamberth, Global Sourcing Manager, **AstraZeneca**
Phil Skelton, Senior Transportation Risk Manager, **ACE European Group**

To join as a panelist, contact courtney.becker@iqpc.co.uk

13.00 Networking Lunch

Track A
QA and Validation

14.00 Developing and Qualifying New Routes and New Packaging for Larger Volumes of Biologic Product

- Understanding the cost drivers
- How to predict stability of biologic products
- Evaluating frozen transportation options
- Comparison with vaccine temperature management
- Meeting regulatory expectations

Tom Bolger, Logistics Specialist**, Genzyme**

14.40 Fine Arts Case Study: Learning from an Industry Where 0% Risk is the Standard

- Challenges of fine arts transport temperature control +20°C
- Risk awareness and comparing approaches on risk handling
- Communication along the transport chain
- Evaluating the impact of shock absorption
- Relating temperature control challenges between pharmaceuticals and fine arts
- Lessons for temperature controlled pharmaceuticals

Hans-Ewald Schneider, President**, Hasenkamp Internationale Transporte GmbH**
Joachim Kuhn, Physicist, CEO and Co-Founder**, va-Q-tec AG**

15.20 Networking Break

15.50 Ensuring an Effective Cool Chain in the Last Mile

- Assessing requirements including validation master plan, routes, timelines to ensure an effective cold chain
- Qualifying shipping systems and assessing suitability
- Adopting a bracketing approach to cold chain validation studies

Nigel Bleakley, Validation Engineer**, UCB Celltech**

16.30 Panel Discussion:
Risk Assessment of the Cool Chain

- When and where does a risk assessment end?
- What exactly do the airlines control?
- Identifying what risks exists at custom points and routes
- There is QA. There is Logistics. But who's responsible for Quality Logistics?

All speakers and participants of this afternoon are invited to join this discussion

17.10 Chair's Closing Remarks

Track B
Blue Sky Room: Cool Chain Process Improvements

14.00 Amgen Continuous Process Improvements in the Cold Chain Case Study: Planning for Long-Term Compliance and Efficient Operations

- Drivers for initiating a Cold Chain Excellence Programme
- Matching transport method with the product and regulatory requirements
- Measuring transport lanes in order to increase performance and optimise costs
- What tools and methods can be implemented to improve control over our third parties (carriers, local stock points)

Martine Nolan, Senior Manager, Quality Assurance, **Amgen**

14.40 Abbott Cold Chain Kiazen Case Study: Improving Storage, Distribution and Transportation Operations

- Drivers for process improvements in our cold chain
- Achieving standardised work processes
- Areas of cost reduction
- Environmentally conscious continuous process improvements

Gert-Jan Van Diest, Cold Chain Manager, Logistics**, Abbott**

15.20 Networking Break

15.50 Implementing a New Warehouse Management System as Part of a Long-Term Strategic Roadmap for Temperature Control

- Drivers for a new WMS system
- Meeting increasing regulatory and customer requirements
- Examples of Beta projects tracking temperature control products throughout the supply chain
- Automating key processes from inbound goods arrival and processing through inventory storage to fulfilling outbound shipping orders
- Developing and using stability tracking data for continuous process improvements

Pier Pollini, Director of Supply Chain Execution, **Baxter Healthcare**

Panel Discussion

16.30 End to End Cool Chain Transportation Processes and the Role of Outsourcing

- New trends in biopharmaceuticals
- How to make processes more solid to minimise human error
- Working with partners that understand what Good Cold Chain Management practices are
- The value of end to end service providers
- Management buy-in – Who is responsible for cost-effective cool chains and outsourcing decisions?

All Blue Sky Room speakers and participants invited to join the discussion

17.10 Chair's Closing Remarks

COOLCHAIN EUROPE 2009

Pre-Conference Specialist Discussions
Forums Tuesday 27 January 2009

8.30 - 11.30

A Understanding International Dangerous Goods Regulations for Hazardous and Biological Material

What you will learn:
- Dangerous Goods regulatory overview and legal implications
- Identification and classification of substances as dangerous goods
- Package specification and UN Testing
- Labeling, marking and documentation
- Operator, state and country variations

How you will benefit:
- Compliant packaging and packaging instructions
- Pharmaceutical shipments
- Clinical trial shipments
- Temperature controlled shipments
- Choosing a risk profile for your biological material shipping
- Comparing import / export challenges and instances and workable solutions to overcome them

Your discussion leaders:
David Walsh, CEO, **DGP Group**
Richard Senior, CEO, **DGP America**

OR

B Considerations for Transporting Temperature Sensitive Pharmaceuticals

What you will learn:
- Documentation audit trail
- Effective procedures to address transport risk issues
- Expectations for real time monitoring
- Effective contingency planning

How you will benefit:
- Gain an appreciation for common errors in truck qualification approaches
- Improve your ability to effectively partner with your carrier to maximize the quality, consistency, and economy of your shipping lane

Your discussion leaders:
Karl Kussow, Manager, Quality and Validation, **FedEx Custom Critical**
Jeff Sitzlar, Manager, Business Development, **FedEx Custom Critical**

11.45 – 14.45

C How to hold your Cool Chain Partners to High Quality Operational Standards: The Cool Chain Quality Indicator (CCQI)

What you will learn:
- Breaking down the cool chain into its links; The Management system; The Master tables; The Benchmarks; The Certification
- Relating the CCQI to specific pharmaceutical industry needs
- Special cool chain requirements in case of pharmaceuticals
- Active temperature control
- Passive temperature control
- GMP / evaluation requirements
- Documentation

How you will benefit:
- How does the CCQI standard cover the special requirements of the pharma industry?
- Is there a need to develop further master tables for the pharma industry?
- Comparing quality standards in different modes of transport – Sea vs. Rail vs. Air vs. Ground

Your discussion leader:
Wilhelm Loskot, Head of Department, Shipping and Logistics, **Germanischer Lloyd Certification GmbH**

OR

D Building Strong Post-Qualification Operational Partnerships to Support Global Cold Chain Supply: Taking Technology From the Lab to Global Supply Operations

What you will learn:
- This workshop will explore how you can implement:
- Inter-company relationship building
- Stock control solutions
- Cross-border supply vs. local supply
- Supporting sustainable networks

How you will benefit:
To ensure successful transition from lab to supply operations, attend this workshop to:
- See examples of existing best supply practices
- Discuss examples of how to eliminate product failures caused by not considering the logistical and supply issues of parts that may require pre conditioning
- Understand how far you can take the aspects of solution supply to further strengthen your cold chain

Your discussion leader:
Nicki Jackson, Operations Manager, **Cool Logistics**

15.00 - 18.00

E Implementing Innovative Shipping Solutions Supporting the Global Distribution of Clinical Supplies

Why you will learn:
With the rise in the global distribution of clinical trials, accompanied by the rising complexity of protocols and the handling requirements associated with biologics and specialty drugs, the need for proactive planning with your supply chain is more critical than ever before. This workshop will cover the following areas:

- Designing pre-qualified systems for clinical trials
- Ensuring quality re-qualification and validation
- Integrating the supply chain: The role of data
- Predicting the future: A look at ongoing development

How you will benefit:
This workshop will explore pragmatic issues.

- How much data should be shared with partners?
- How to monitor through data: Excursions and successes
- What is the answer for cold chain packaging for international IMPs? How can we balance cost without over-engineering
- Understanding how to comply with guidance on ordering, shipping, and returning clinical supplies.

Your discussion leader:
Rognvald Lamb, EMEA Logistics Manager, **Fisher Clinical Services**

OR

F Evaluating Reusable and Recyclable Packaging for your Cold Chain Logistics

What you will learn:
- Regulations on cold chain and reusable packaging
- Minimising number of shipment is one way to reduce cost and improve environmental consequences
- Understanding perceived cost issues
- Estimating the initial investment vs. long term value gains

How you will benefit:
- Select the right thermo packaging for the job
- How to integrate in your logistic management the unlife packaging concept: One way or/and Reused?
- Utilise unlife packaging to balance costs, security and environmental impact of your cold chain operations

Your discussion leader:
Gilles Labranque, Chairman & Managing Director, **Sofrigam**

COOLCHAIN EUROPE 2009

Pre-Conference and Post-Conference Events

Pre-Conference Evening Seminar

Tuesday 27 January 2009 - 18.15 - 21.15 (light supper served)

Assessing Opportunities and Overcoming Challenges in New Markets: China, India and Africa

As China is now part of WTO, the FDA has set up an office to monitor pharmaceutical manufacturing, transport and product quality. This timely seminar reflecting today's current challenges will be a valuable opportunity to examine current challenges in meeting regulatory requirements.

Session I
Shipping Vaccines in Emerging Economies

- Understanding the structure of distribution chains and differences between manufacturers, distributors and government handling vaccines
- Cold Chain logistics challenges - vaccine storage, distribution, handling at point of use
- Taking lessons from recent experiences in Nigeria - Is it possible to plan for the worst?
- Conducting field assessments and identifying problems Identifying risks and taking steps to minimize them

Anthony Battersby, Partner, **FBA Health Systems Analysts**

Session II
Overview of the Indian market: shipping temperature sensitive pharmaceuticals in/out and handling customs challenges

- Regulatory expectations for this new pharmaceutical market
- Overcoming challenges in getting continuous shipments out of India
- Developing a trusted network of supply chain and transport partners

Session III
Training Chinese Affiliates to Ensure Product Safety, Transport Effectiveness, and Packaging Qualification

Wyeth has recently embarked on a new venture training a Chinese affiliate who is distributing their product. Pack outs are different, the supply chain is more complex, their 'cold chain systems' are extremely basic. In this session, Richard will relay their experiences in training Chinese distributors on re-qualifying shippers, including a look at the use of passive systems and the trials and tribulations of getting their very outdated systems up to speed with modern technology, regulations and complex supply chains.

- Overall impressions and differences noted of temperature controlled pharmaceutical shipping in China
- Redefining cold chain processes from 'old' methods to modern
- Packaging technology used, available, changed and validated
- Making heads and tails of new international regulatory requirements

Richard Peck, Cold Chain Technology Lead, **Wyeth**

Post-Conference Practical Problem Solving Training

Friday 30 January 2009 - 9.00 - 15.00

Planning your Cool Chain Management for Today's Challenges

Attend this interactive day to find out what methodologies and solutions other companies are implementing to benchmark your practices to industry best practices in cold chain management. A range of presentations, small break out group discussions and case studies will be used so you can update your practices to reflect today's challenges for new product temperature ranges, global cold chains and international regulations.

8.45 Registration

9.00 Morning Sessions

- Ask specific questions to expert authorities in an interactive forum
- Share experiences, stories and mistakes with other pharmaceutical manufacturers and cold chain stakeholders
- Learn about the latest trends and technology in the cold chain, and which ones have been accepted and implemented

Setting up your Cold Chain Internally

- Senior Management buy in, budgeting
- Making the business case
- Comparing cost vs. business value

Transport Systems Available Today in Europe and Internationally

- Examining trends in modes of transport being used in Europe
- Identifying sea transport providers and working with freight forwards to consider this option for finished products
- Examining equipment on trucks
- Comparing actual cold chain shipment scenarios for air, sea, rail and ground by:

- Cost
- Speed
- Validation
- Fuel Surcharges

Temp Recorder Systems, Loggers

- Avoid excursions by learning how to update your temperature mapping and profiling for each and every route and their climates

12.00 Lunch

12.45 Afternoon Sessions

Auditing of 3PLs and GDP Shipping Agreements

- Selection of suppliers
- How to manage temperatures
- Examining the standard of trucks
- Set expectations early
- Procedures, instruction, forms preparation and training
- Defining standards? (company vs. regulatory)
- Communication channels and contact points
- Quality agreement vs. service agreement

Training Healthcare Partners

- Educating people handling your products
- GDP/GMP education for 3PLs (who is going to do it?)
- Training on agreed procedures

Qualifying and Validating your Routes

- Choosing the right lanes
- Best practices in qualification of routes
- Collecting stability data to feed into decisions
- Monitoring temperature on route!

15.45 End of Training

About your Trainer:

Dr. Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd., formerly Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline, provides consultancy services to the companies within the pharmaceutical and biotechnology supply chain. Afshin is a QP via permanent provision with detailed working knowledge of European and FDA regulatory requirements with over 20 years of experience of auditing pharmaceutical manufacturing sites across Europe and USA, as well as preparation for and fronting of EU and FDA regulatory inspections. Afshin is a member of the UK standards committee for development of the ISO GMP standards for packaging components. Afshin is acknowledged expert in quality management system for pharmaceutical supply chain, he is currently advising companies on developing and validating Cold Chain Supply process, and is a regular speaker at Pharmaceutical industry conferences in Europe and the USA. Afshin is visiting lecturer at the London Metropolitan University

Who is this Training for?

Whether you're new in the cold chain, or been involved for several years, this practical training session will bring you up to speed with how companies are re-engineering the cold chain management for today's challenges. You will share ideas with professionals in:

Supply Chain Managers • QA • Logistics • Procurement • R&D • Transport • Regulatory

Sponsors and Exhibitors

Session Sponsors

Tel: +44 1094 607 390
Fax: +44 1094 607 391
Email: compliance@dgpgroup.com
Web: www.dgpgroup.com

Tel: +33 1 46 69 85 00
Fax: +33 1 47 25 98 44
Email: sofrigam@sofrigam.com
Web: www.sofrigam.com

Temperature Controlled Services
Tel: +1 888-274-2901
E-mail: airexpedite_tempassureair@fedex.com
Web: www.customcritical.fedex.com

Tel: +44 (0)1403 212700
Fax: +44 (0)1403 212712
Email: vision@thermofisher.com
Web: www.fisherclinicalservices.com/

Tel: +49 931 35 942 0
Fax: +49 931 35942 10
Email: info@va-Q-tec.com
Web: www.va-q-tec.com/english/products/packaging.html

Panel Session Sponsor

Tel: +31 252 211108
Fax: +31 252 231032
E-mail: cvo@sensitech.nl
Web: www.sensitech.com

Gold Sponsor

Tel: +49 711 900 597 912
Fax: +49 711 900 597 910
E-mail: contact@movianto.com
Web: www.movianto.com

Featured Exhibitors

Tel: +49 (0) 52 41 80-40378
Fax: +49 (0) 52 41-80-6-40378
E-mail: contact@arvato-services-healthcare.com
Web: www.arvato-services-healthcare.com

Tel: + 31 (0)252 245 200
Fax: + 31 (0)252 245 222
E-mail: info@topa.nl
Web: www.topa.nl

Tel: +41 81 750 03 11
Fax: +41 81 750 03 17
E-mail: swiss@elpro.com
Web: www.elpro.com

Tel: +44(0)118 932 5000
Fax: +44(0)118 932 5001
E-mail: katie.friday@kryotrans.com
Web: www.kryotrans.com

Tel: +41 (0) 71 982 88 11
Fax: +41 (0) 71 982 88 39
E-mail: info@berlinger.ch
Web: www.berlinger.ch and www.freeze-tag.com

Tel: +33 (0) 474 09 10 80
Fax: +33 (0) 474 67 60 93
E-mail: isostar@emballiso.com
Web: www.emballiso.com

Tel: +49 69 696 40920,
Fax: +49 69 696 98 40920
E-mail christopher.dehio@dlh.de
Web: www.lhcargo.com

Tel: 0032 2 460 77 55
Fax: 0032 2 460 60 45
E-mail: info@exampackaging.com
Web: www.exampackaging.com

Tel : +32 (0)2 712 50 80
Fax : +32 (0) 712 50 89
E-mail: sales@worldcourier.com
Web: www.worldcourier.com

Tel: +46 18 34 73 00
Fax: +46 18 38 42 80
E-mail: sales@envirotainer.com
Website: www.envirotainer.com

Literature Distribution Sponsor

Cathay Pacific Airways, Ltd
Web: www.cathaypacificcargo.com
E-mail: Jack_Lo@cathaypacific.com

Workshop Sponsor

sca-cool-logistics

Tel: +44 (0)1525 243770
Fax: +44 (0)1525 243779
Email: cool.info@sca.com
Web: www.sca-cool-logistics.com

Kalibox

Tel: +33 (0)3 44 63 40 40
Fax: +33 (0)3 44 63 02 40
E-Mail: contact@kalibox.fr
Web: www.kalibox.eu

laminarmedica
insulated shipping systems

Tel: +44 (0)1442 828664
Fax: +44 (0)1442 827056
E-mail: enquiries@laminarmedica.co.uk
Web: www.laminarmedica.co.uk

KERN FRIO
Insulated Packaging Solutions

Tel: +(34) 93 366 -1025
Fax: +(34) 93 366 -1028
E-mail: pcapizzi@kernfrio.com
Web: www.kernfrio.com

Softbox

Tel: +44 (0) 1844 203560
Fax: +44 (0) 1844 203570
E-mail: mark.hammond@softboxsystems.com
Web: www.softboxsystems.com

Sponsorship and Exhibition Opportunities

Pharma IQ's Cool Chain Europe will provide the perfect platform for freight, logistic, storage, packaging and temperature control companies to profile their offering to senior level decision makers from bio-pharmaceutical companies – bringing together the largest gathering of buyers and suppliers of temp control solutions in one location. For more information, please contact Gal Cohen on **+44 (0)20 7368 9491** or email **gal.cohen@iqpc.co.uk**

> "The Brussels cold chain event has become a key conference in the calendar. The mix of attendees and discussions have made it more than just another event on the calendar, but something that provides real discussion, interaction and opportunity"
> Thermo Fisher

> "Very valuable, great educational and networking forum"
> Acutemp Thermal Systems

Media Partners

Supply Chain Europe **www.scemagazine.com**

Pharma **www.pharmamag.com**

Euro Pharma Contractor **www.samedanltd.com**

PMPS **www.samedanltd.com**

Cool Chain Association **www.coolchain.org**

InPharm **www.inpharm.com**

PharmaFocus **www.pharmafocus.com**

Pharmaceutical Insight **www.pharmaceuticalsinsight.com**

Cool Pack **www.coolpack.com**

COOLCHAIN EUROPE 2009

January 27-30 2009

Sheraton Airport Hotel, Brussels, Belgium

REGISTRATION FORM

To speed registration, please provide the priority code located on the mailing label or in the box below.

My registration code is **PDFW**

Please contact our database manager on +44(0) 207 368 9300 or at database@iqpc.co.uk quoting the registration code above to inform us of any changes or to remove your details.

CONFERENCE PRICES

✓		Book by 7th November*	Book by 5th December*	Standard Price
	All Inclusive Package Conference+ Choice of 3 out of 6 Specialist Discussion Forums + Seminar + Training Limited offer available to only first 10 registrants before 7th November	Save €1500 €4924 + VAT	€6424+ VAT	
	Conference + 3 Specialist Discussion Forum +Dinner	Save €450 €4146+ VAT	Save €350 €4246+ VAT	€4596+ VAT
	Conference Only + Dinner	Save €150 €2049+ VAT	€2199+ VAT	
	Conference Only (CEE Countries**) + Dinner	€1699+ VAT		
	Post-Conference Practical Training Only	€1029 + VAT		
	Specialist Discussion Only (one)	€799 + VAT		
	Seminar Impact China Only	€799 + VAT		

Please select your Specialist Discussion Forum choices: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F Academic and non-profit discount of 50% available

*Payment must be received with bookings to qualify for discounts. Belgian VAT VAT/TVA is charged 21% where applicable
*Only one discount is applicable per person. In order to qualify for discounts, bookings must be received with payment by the early bird dates

Excellent Group Discounts of up to 25% available– enquire on +44 (0)20 7368 9300

All 2-day conference registrants are welcome to attend the Networking Gala Dinner and Awards Evening on 28th January (included in your conference package)

☐ Please tick here to opt out of the Awards Dinner and reduce conference price by €50 (if registering online, please let your customer service representative know upon booking).

**Central and Eastern European Countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Slovenia, Ukraine, Yugoslavia, Serbia and Montenegro, Turkey, Macedonia, Georgia, Kazakhstan, Moldova, Uzbekistan

CANCELLATIONS AND SUBSTITUTIONS

PAYMENT TERMS Payment is due in full upon completion and return of the registration form. Due to limited conference space we advise early registration and payment by credit card to avoid disappointment. Your registration will not be confirmed until payment is received. Payment of invoices means other than credit card, or purchase order (UK Plc and Government bodies only) will be subject to a €65 (plus VAT) processing fee.

CANCELLATION AND SUBSTITUTION POLICY Provided the fee has been paid in full, substitutions at no extra charge can be made up to 7 business days before the start of the conference. Cancellations must be received in writing or by fax to +44 (0)20 7368 9301, more than 7 days before the conference is to be held in order to obtain a full credit for any future conference. Cancellations received 7 days or less (including the seventh day) prior to the conference will not be credited. In the event that IQPC cancels an event payments received at the cancellation date will be credited towards attendance at a future conference, or in the event of postponement by IQPC, a rescheduled date. Credit notes remain valid for twelve months. IQPC reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. IQPC is not responsible for any loss or damage as a result of substitution, alteration, postponement, or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism, or hostilities. SPEAKER CHANGES Occasionally it is necessary for reasons beyond our control to alter the content and timing of the programme or the identity of the speakers

DATA PROTECTION Personal data is gathered in accordance with the Data Protection Act 1998. Your details may be passed to other companies who wish to communicate with you offers related to your business activities. If you do not wish to receive these offers, please tick the box below. ☐ Please do not pass my information to any third party

TEAM DISCOUNTS

Bonus team discounts!

Teams of 3 receive **10% off** | Teams of 4 receive **20% off** | Teams of 6+ receive **30% off** | Teams of 8+ receive **35% off**

DELEGATE DETAILS

Please photocopy for each additional delegate

DELEGATE 1

☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Dr ☐ Other First Name

Family Name Department

Position Tel No.

Email

☐ Yes I would like to receive information about products and services via email

Organisation

Nature of business

Address

Postcode Country

Telephone Fax

Dept. Head Title

Name of person completing form if different from delegate:

Signature

I agree to IQPC's cancellation, substitution and payment terms

Special dietary requirements: ☐ Vegetarian ☐ Non-dairy ☐ Other (please specify)

Please indicate if you have already registered by Phone ☐ Fax ☐ Email ☐ Web ☐

Please note: if you have not received an acknowledgement before the conference, please call us to confirm your booking.

PAYMENT METHODS

Cheque enclosed for : *(Made payable to IQPC Ltd.)*

By Direct Transfer: (Please quote 11399.002 with remittance advice)

IQPC Bank details: HSBC Bank - Sort Code: 40 05 15, Account no: 59090618, IBAN No: GB98 MIDL 4005 1559 0906 18,

BIC: MIDLGB22, Account name: International Quality & Productivity Centre Ltd

By Credit Card: Please debit my credit card: ☐ VISA ☐ AMERICAN EXPRESS ☐

Card No Expiry date

Sec No Cardholder's name Signature

Card billing address *(if different from Co. address)*

Country Postcode

DIGITAL CONFERENCE ON CD ROM

A digital version of the conference proceedings, including all the presentations in audio format *"An excellent service, an invaluable reference tool, easy to access and easy to store - all in all a top product"*

Recent digital conferences available - £599 plus VAT each

☐ **Pharma Secure Chain - October 21-22 2008**

☐ **End 2 End Supply Chain - October 21-22 2008**

Please send me conference materials indicated above. I have filled out credit card details.

For further information Please call: 0207 368 9300 or email knowledgebank@iqpc.co.uk.
To search IQPC's archived conference documentation visit: www.iqpcknowledgebank.com

VENUE & ACCOMMODATION

VENUE:
Sheraton Brussels Airport Hotel and Conference Centre
1930 Zaventem
Brussels, Belgium
Tel: 32-2-710 80 00 Fax: 32-2-710 80 80
Website: www.sheratonairport.be

ACCOMMODATION:
Hotel accommodation is not included in the registration fee. A limited number of reduced rate rooms are available at The Sheraton Airport Conference Centre, Brussels: To book accommodation at The Sheraton Airport hotel, Brussels, to book online click: http://www.starwoodmeeting.com/Book/coolchain. Prices from €195.00 standard single including vat and breakfast. For alternative accommodation in Brussels, search **www.cityhotelaccommodation.com/brussels.html**

GB VAT reg. number 799225967