CONFERENCE DAY 1

Tuesday 28th January 2014

08.00 **Registration & Networking Coffee**

08.45 **IQPC Welcome and Chairman's Opening Remarks**

08.55 **Welcome Remarks Ministry of the Economy and Foreign Trade, Luxembourg**

Minister of the Economy and Foreign Trade, Luxembourg

09.00 **KEYNOTE: Preparing for Life Science Supply Chain Growth in an Ever-Changing Global Economy and Pharmaceutical Business**

- The evolving biopharmaceutical organisation
- Increased international outsourcing and its impact to the supply chain
- Major challenges and opportunities for pharmaceutical companies today in Europe
- Five to ten year outlook: how we will operate as a global industry

Erica Monfardini, PhD., Director, Pharma & Life Sciences, **PwC Luxembourg**

09.20 **KEYNOTE: Developing a GDP Certified Logistics Infrastructure**

Understanding the role of infrastructure in creating an end-to-end temperature controlled supply chain

- Complying with airfreight requirements: the implications for pharma companies
- Luxembourg case study: creating a fully compliant, qualified and certified airfreight hub according to the latest WHO and EU GDP guidelines

Daniel Liebermann, Director, Directorate Logistics, Ministry of the Economy and Foreign Trade, **Luxembourg**

LUXEMBOURG LOGISTICS FOCUS

09.50 **Collaborating to Ensure a GDP Compliant Cool Chain**

- Impact of GDP and its challenges on carriers
- The critical importance of engaging with supply chain stakeholders
- Designing appropriate transport and storage equipment
- Key aspects for a successful cool chain

Robert van de Weg, Senior Vice President Sales & Marketing, **Cargolux**

10.20 **INDUSTRY KEYNOTE CASE STUDY**

Reducing Lead Times and Maximising Efficiency through Developing a Geographical Zoning Approach

- Introduction to GeoZone Principles
- Taking a qualification approach
- Best practice lane mapping and protocol development
- Effective approaches to business risk mitigation
- Track and trending of shipments
- Core aspects to be covered in the annual review

Graham Martin, Supply Chain Excellence Manager, **Pfizer**

10.50 **Networking Coffee Break**

11.30 **Breakout Roundtable Sessions**

Simply choose the roundtable topic of most interest to you and join in the discussion. These sessions are open, informal and a great opportunity to really gauge what your peers are planning and to share ideas and lessons learned. You will walk away with tangible ideas on how to solve your biggest challenges. Due to popular demand, there is an opportunity to attend two roundtables, as they are all repeated at the same time on the second day.

- **TABLE A: Evaluating the Benefits and Practicalities of a Less than Load Approach**
- **TABLE B: Making Sense of the Falsified Medicines Act**
- **TABLE C: 2-8C Sea Freight Practical Realities and Solutions**
- **TABLE D: Shipping to China: Challenges Shared by the Industry**
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- **TABLE H: Mix-Load Trailers: How to Manage Multiple Temperature Payloads in the Same Truck**

12.30 **Networking Lunch Break**

CONCURRENT STREAMS
PLEASE CHOOSE ONE:

STREAM A: Life Science Global Supply Chain Forum

13.30 **Quick Win Networking**

An opportunity to exchange business cards with colleagues focusing on supply chain integrity

13.35 **Protecting your Global Supply Chain (TAPA): Why a proactive partnership between manufacturer and LSP is key to success within an end to end supply chain solution**

- TAPA and other global standards for cargo security
- Identifying security risks through investigation and process auditing
- Case studies: a high-value electronics industry perspective and global logistics security experience

Thorsten Neumann, Director Corporate Security, **Nokia** & Chairman **TAPA EMEA**

STREAM B: Applying Risk Analysis to Logistics and Improving Process Optimisation

13.30 **Quick Win Networking**

An opportunity to exchange business cards with colleagues focusing on global logistics

CASE STUDY: Analysis of Global Logistics Processes to Reduce Temperature Excursions

- Cost vs. quality vs. risk: the new paradigm in temperature controlled logistics
- Developing a risk based shipping lane
- Using historical data and lane tests to assess where risk is highest across the supply chain
- Driving cost efficiency through applying temperature control to highest risk areas
- How much risk should we be taking?

Ruud van der Geer, Senior Specialist, Distribution and Global Logistics Centre of Excellence, **Merck Sharpe and Dohme**

STREAM C: GDP Updates by Chapter

13.30 **Quick Win Networking**

An opportunity to exchange business cards with colleagues focusing on GDP regulations

ARMCHAIR INTERVIEW: What's New? What's Changed? The Regulatory Perspective

A candid, open interview with a regulatory representative…too good to be true?
This is a unique opportunity to hear an independent industry expert interview a regulator to delve deeper into the questions surrounding the new GDP regulations and what the future holds for the life sciences logistics industry.
QUESTION TIME!
You will have the chance to submit your questions to the interviewer in advance, they will be reviewed and the best ones picked to be asked during the session

Riekert Bruinink, Group Chairman of the PIC/S GDP Working Group, Member of the EMEA GDP Drafting, **Dutch Health Care Inspectorate**

	STREAM A: Life Science Global Supply Chain Forum	STREAM B: Applying Risk Analysis to Logistics and Improving Process Optimisation	STREAM C: GDP Updates by Chapter
14.05	**5 minute change over**		
14.10	**DEBATE: What Should the Role of the Logistics Provider be in Data Collection and Analysis?** The pharma supply chain is a complex environment with a considerable number of stakeholders involved, all have the potential to collect and store data along the way but do you need your own data collection strategy or can you rely on your logistics providers? Some points for discussion; • Who owns the data? • Can you really achieve harmonised and central storage of data from multiple sources? • Regulatory implications of multiple sources of data • Do logistics providers have any obligation to collect data? • Quality oversight and management of logistics service providers • Transportation vs. product "interests" and requirements • Who pays for it? Moderator: **Benjamin E. Blumer,** Supply Chain Manager, **Horizon Pharma AG** Panellists: **Simon White,** Director Quality Operations, Global Logistics & Supply, EMEA Region, **Pfizer** **HARNESSING THE POWER OF LOGISTICS DATA**	**Case Study: Logistics Process Performance Management** • Consolidate, optimise, execute – our strategy • Influencing internal teams to improve their processes as well • The impact of temperature control on supply chain processes including lead times, collaborative planning, forecasting and capacity in fleets **Julian Wann,** Global Category Manager, Freight & Logistics, **AstraZeneca** **GLOBAL LOGISTICS OPTIMISATION INITIATIVES**	**TASK FORCE: In Practice: What does EU GDP Chapter 9 on Transportation Mean in Day-to-Day Operations?** Chapter 9 Principle; *'It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.* *Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.'* This is the introduction to what is arguably the biggest change the industry has seen in years. Do you fully understand all of the implications within chapter 9? How are your contemporaries approaching these new requirements? This session will provide a unique platform to discuss best practices for storage and transport of controlled room temperature products. The submitted ideas will be documented and distributed to all involved in the taskforce to review post event. There will also be follow up each quarter. Task Force Contributors: **Stephen Mitchell,** Quality & Compliance Manager, **GlaxoSmithKline; Simon White,** Regional Leader, Quality Operations, EMEA, Global Logistics & Supply, **Pfizer** **GDP REGULATORY UPDATES BY CHAPTER**
14.40	**5 minute change over**		

	STREAM A: Life Science Global Supply Chain Forum	STREAM B: Applying Risk Analysis to Logistics and Improving Process Optimisation	STREAM D: Partnerships, Collaborations and Improving Supplier Relationships
14:45	**What is the True Potential of Supply Chain Data and How Do we unlock it?** Presentation details (tbc) **Christine Foster,** Global QA Audit Manager, **AstraZeneca**	**Evaluating Solutions for the Most Challenging Products: Sea Freight 2-8° and Air Freight RT°** • No choice but to comply with CRT and ambient product requirements today • Comparing cost and features of pallet covers for temperature maintenance • Sea freight 2-8° major challenges, temperature spikes and new data from thermal covers • Air freight CRT°: comparing cost and data of using passive shippers vs. pallet covers • Examples of CAPA to overcome problems at certain destinations **Shirley Feld,** Deputy Director, Global Quality Supply Chain, **Sanofi-Aventis**	**Tightening Global Processes with Logistics Partners for High-Value, High-Security Temperature Control Products** • Meeting of minds: visiting airlines, 3PLs and security companies to get agreement on technical agreements and SOPs • When it goes wrong: establishing contingency plans that work • Developing intelligence for new shipping lanes and for particular regions • Documenting the process: the challenges • Case study examples: Latin America and Middle East **Henry Moran,** UK and International Supplies Manager, **Napp Pharmaceuticals**
15.15	**5 minute change over**		

15:20 **Effectively Setting Up and Rolling Out a Standardized Global Temperature Monitoring and Data Collection System**

- Evaluating prerequisites, user requirements, selection and qualification
- Centralized set-up and provision of temperature data logger profiles
- Centralized archiving of PDF reports and forwarding of alarm PDF reports
- Description of temperature monitoring process in a corporate SOP
- Roll out / training of temperature monitoring process
- Trending: how to effectively apply this data
- Next steps

Robert Müller
Senior Global Logistics Manager, Global Logistics & Customs
Boehringer Ingelheim

CASE STUDY: Pilot Results: Shipping 4C Bulk from Global Suppliers via Ocean

- The process for defining our test criteria and defining best practices
- Discussing opportunities and protocols with logistics partners
- Experience of working with global suppliers in markets such as Brazil
- Impact of sourcing supplies globally on the quality of transportation and quality of freight

Jos Hanssen, Logistics and Distribution Director, **Ossur**

GLOBAL LOGISTICS OPTIMISATION INITIATIVES

Balancing the Need for Supply Chain Partners to Innovate with the Slow Moving Wheels of Big Pharma to Adopt

- What drives change in Cold Chain distribution (compliance / cost/ other)?
- What does big pharma need from suppliers to enable change?
- What effect will GDP have on pharma's ability / desire / adoption of change?
- How can Pharma engage more effectively with the supply chain partners to understand their perspective?
- Definition of partnership is "an arrangement in which parties agree to cooperate to advance their mutual interests" do they really exist and what is the benefit if any?

Moderator:
Steve Healy, Global Director of Sales, **DGP Intelsius**

Panelists:
Erik Agterhuis, Distribution & Warehouse Manager Global Distribution, **Abbott**
Ruud van der Geer, Senior Specialist, Distribution and Global Logistics Centre of Excellence, **Merck Sharpe and Dohme**
Sarah Mahon, Global Distribution and Customer Service Director, **Ipsen**
Don Riach, Strategic Development Director, **Biocair**
Graham Martin, Cool Chain Strategic Development Manager, **Pfizer**

15.50 **5 minute change over**

16.15 **PANEL DISCUSSION: Supply Chain Visibility and Continuous Process Improvement**

Since the publication of the new EU GDP on March 7, 2013, there has been an increased focus on the implementation of Quality Management Systems (QMS) used to document, assess, control, communicate, and review actual performance against defined Quality Agreements. The implementation of Continuous Process Improvement and well known Corrective Action / Preventative Action (CAPA) and relentless Root Cause Analysis (RCA) techniques are now firm expectations for the storage, handling, and distribution processes. This panel session will include:

- Benchmarking between companies what risk management best practices are needed to achieve supply chain visibility
- Software and data logging tools used to document and manage the complex pharmaceutical supply chain
- Pharmaceutical case studies: achieving greater supply chain visibility and control in global logistics
- Exploring the future direction of the industry: what's next for logistics data management?

Moderator:
Henry Ames, VP Strategy and Business Development, **Sensitech**
Thorsten Neumann, Director Supply Chain Security and Chairman, **Nokia and TAPA**
Tony Kavanagh, Brand Protection Manager, **SanDisk**

16:25 **Networking Coffee Break**

17.00 **Improving the Performance of Your Temperature Control Packaging**

- The current methods used for establishing temperature controlled packaging performance, along with the associated pros and cons
- Using a new method to define shipping system performance and enable better choices for the correct shipper for a particular route
- Taking a collaborative approach: what you can do as a customer or collaborative partner to feed back data and information to improve shipping system performance and improve control of your products
- Calculating the ambient stress that the shipper will be exposed to so the best solution is used for that product and lane
- Can the industry work toward a single, universally agreed standard to appraise packaging performance?

Richard Wood, Design Manager, **Cool Logistics**

17.30 **The Impact of Temperature and Other Parameters on the Quality of Biological Samples**

- Understanding Cryopreservation and handling for biological samples
- Working with logistics partners to ensure quality control of bio specimens
- Logistics and the pharmaceutical industry
- Equipment and facility costs and risks of frozen drug substances

Dominic Allen, Director, **Integrated Biobank of Luxembourg**

18.10 **Cool Chain Excellence Award Ceremony**

Nominations are now open! For all of the criteria and submission materials please visit
www.coolchaineurope.com/awards or call +44 (0)207 368 9300

COOLCHAIN Excellence Awards

18.40 **Networking Drinks Reception and Casino Night**

CONFERENCE DAY 2

Wednesday 29th January 2014

08.00 **Registration & Networking Coffee**

08.30 **Chairman's Recap**

08.40 **KEYNOTE: Quality Control in Emerging Markets and Global Supply Chains**

- Logistics challenges growing into emerging markets: quality, local regulatory requirements and security issues
- Vetting your sources, trading partners and affiliates to ensure compliance and quality control
- How to manage the integrity of products throughout transportation
- Evaluating solutions to gain more quality control in global supply chain processes

Sam MacHour, Global Vice-President for Quality & Compliance Operations, **Becton Dickinson**

NEW MARKET INSIGHTS AND INDUSTRY SOLUTIONS

Acclimatising to Controlled Room Temperature and Ambient Logistics Requirements and the New EU GDPs

09.10 **Practical Implications of Distributing Controlled Room Temperature & Assessing the Impact of CRT in Last Mile Distribution**

- The new 15-25C requirements in the EU mean an increase in products during the last mile that will need temperature control measures
- Delivery direct to pharmacy challenges
- Conducting risk analysis and test shipments to prove compliance
- Working together as an industry to improve temperature control in the last mile

Gerwin van Harskamp, Head of EMEA Distribution and ELC Customer Service, **Bausch + Lomb**

ALL THINGS ROOM TEMPERATURE AND CRT

09.40 **BENCHMARKING PANEL: The Practicalities and Top Priorities of Controlled Room Temperature Logistics**

This interactive panel session brings together the regulatory, end user and supplier perspective on;

- Definitions of CRT according to the new GDP requirements
- What impact this has had on business and logistics choices?
- New strategies that have been implemented so far
- Educating global transport teams and transport chain use EU CRT GDP requirements
- Challenges in proving control to regulatory authorities
- Lessons learned

This is the perfect opportunity to discuss your challenges, refine the solutions you are using/considering and benchmark with your peers. Ask your questions to our expert line up and the wider community!

Panellists: **Shirley Feld,** Deputy Director, Global Quality Supply Chain, **Sanofi-Aventis; Isabelle Angehrn,** Project Lead, Temperature Controlled Supply Chain, **Roche**

ALL THINGS ROOM TEMPERATURE AND CRT

10.20 **Breakout Roundtable Sessions**

Simply choose the roundtable topic of most interest to you and join in the discussion! These sessions are open, informal and a great opportunity to really gauge what your peers are planning and to share ideas and lessons learned. You will walk away with tangible ideas on how to solve your biggest challenges. Due to popular demand, there is an opportunity to attend two roundtables, as they are all repeated at the same time on the second day.

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11.15 **Networking Coffee Break**

CONCURRENT STREAMS. PLEASE CHOOSE ONE:

STREAM A: Life Science Global Supply Chain Forum

12.00 **Simultaneous One-on-One High Level Business Meetings**

The business meetings provide an exceptional opportunity for event participants to assess the solutions and services that are available to help them achieve their business objectives. For a full list of the confirmed solution providers participating please visit our solution provider's page or if you have any questions please get in touch!

12.05 **The Impact of Cold Chain and CRT on Supply Chain Planning**

- CRT move from air to ocean – knock on affects on lead times and forecasting
- Capacity in fleets – are there enough trucks for CRT products?
- How is collaborative planning changing with such demands the supply chain?

Gianpiero Lorusso, Supply Chain Manager, **Merck Serono**

STREAM B: Qualification of CRT Packaging and Quality Supply Chains

Quick Win Networking

An opportunity to exchange business cards with colleagues focusing on CRT

Quality Risk Management in Distribution: A Road Freight QA Case Study

- Evaluating lanes for duration, temperature spikes, in certain climate zones to fully characterise specific lanes
- Assessing product stability data to determine acceptable temperature ranges for transport
- Communicating risk-based initiatives and controls to global affiliates ,manufacturing sites and transport teams

Simon White, Director Quality Operations, Global Logistics & Supply, EMEA Region, **Pfizer**

STREAM E: Exploring the Ups and Downs of Supply Chains in Emerging Markets

Quick Win Networking

An opportunity to exchange business cards with colleagues interested in emerging markets

INDUSTRY THINK TANK: Building a Bridge from India to Europe: Creating a Unified Industry Approach

Pharmaceutical companies are increasingly shipping product and materials out of India. Each company is developing their own, isolated solutions, yet all companies across industry are facing the same challenges!

This discussion will focus on how industry can collaborate to find more unified, robust and cost-effective solutions for shipping temp control from India to Europe, including:

STREAM A: Life Science Global Supply Chain Forum

STREAM B: Qualification of CRT Packaging and Quality Supply Chains

STREAM E: Exploring the Ups and Downs of Supply Chains in Emerging Markets

12.35 **5 minute changeover**

12.40

COLLABORATIVE PANEL DISCUSSION: Air Freight Logistics Handling: Keeping up with New Solutions and Increasingly Global Supply Chains

- Improving CRT passive shipping logistics processes – what can each stakeholder do?
- What do the pharmaceutical manufacturer and the 3PL expect from each other to ensure quality control handling of air freight?
- Processes for managing deviations, performing investigations and implementing corrective and preventive actions
- Treatment of shipments during custom clearance and timely customs clearance lessons learned
- Live tracking of products in the air: reality or pipe dream?

Moderator:
Roel Reynders, Senior Director Quality for Supply Chain and Affiliates, **Merck Serono**
Alan Dorling, Global Head - Pharmaceuticals & Life Sciences **IAG Cargo at International Airlines Group**
Peter Lockett, Director, **TP3 Global**
Kaoutar Lenstra, Senior Cold Chain and Specialties Analyst, **Pfizer**

IATA New Auditing Principles for Air Freight Quality Processes

Andrea Gruber, Manger, Business Process and Standards, **International Air Transport Association (IATA)**

- Current solutions available shipping temp control cargo India to Europe and their limitations
- LTL hubs in Mumbai – why are we all building the same thing?
- Local 3PLs vs Global 3PLs: Assessing local capabilities vs. established international processes

Discussion Co-Leader:
Val Petursson, Executive Director of International Logistics, **Actavis**

NEW MARKET INSIGHTS AND INDUSTRY SOLUTIONS

13.10 **Networking Lunch**

14.10

Establishing Quality Distribution & Risk Management Processes

- Examining the implications of the interdependence of all stakeholders involved in the global pharmaceutical supply chain
- Considerations regarding impacts of increased regulatory oversight
- Best practice approaches to risk management
- Cost savings vs. quality within pharmaceutical distribution

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

CASE STUDY: Sea Freight Process and Validation Study

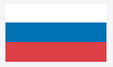
- Sea freight qualification for cold chain 2-8 products
  - Business stakeholders and risk management
  - Principles of the qualification approach
  - Lane mapping and protocol development
  - Business risk analysis: quality and cost
- Sea container qualification
  - Case study – MIRA UK test chambers
  - Thermal insulation systems to minimise risk
- Next steps to implementation

Graham Martin, Supply Chain Excellence Manager, **Pfizer**

DISCOVERING RUSSIA Distribution Practices in Russia: Lead Auditor Perspective

- Current storage and distribution legislation in Russia
- Main quality deficiencies found during GDP audits of wholesalers and clinical depots
- Practical elements to include in supplier site audits to ensure quality control
- How to ensure Quality Agreements are followed and executed property
- Opportunities for industry developments in cool chain management – the 5 year outlook

Mikhail Khazanchuk, RA & QA Manager, **Novo Nordisk Russia**



14.40 **5 minute change over**

14.45

Using Science to Improve Future Cold Chain Shipping Solutions

- An engineering system that needs to be measured, controlled, and evaluated
- The impact of permeability on packaging qualification
- Developing new modelling software to go through continuous improvement system, reduce time-to-market and increase efficiency of cold chain shipping containers

Gilles Labranque, CEO, **Sofrigam**
Frédéric Kuznik, Lecturer, **Thermal Sciences Center of Lyon (CETHIL)**

CASE STUDY: Air Freight Route Qualification for 15C - 25C from Europe to US

- Regulatory background, why do we do qualifications?
- Qualifications in transportation, subject and methodology
- Qualification challenges - understanding air freight (multimodal) system complexity.
- Prequalification risk assessment exercise
- Qualification exercise, conclusion and new knowledge

Zvonimir Majic PhD., Head of Quality Assurance EU Logistics, **Teva**

DISCOVERING RUSSIA Partnerships Matter! Cool Chain Management at Each Level of End-to-End Supply Chain (from Producer to Patient) - Practical Examples of Finding the Right Way

- Latest tendencies of the Russian market and business development including portfolio increase (vaccines, surgical clue), "new" temperature regimes intro (-18; -80), quality and risk management, costs increase management
- Partners readiness assessment from J&J practices including warehouse, transport, customs, distributors infrastructures; patients organisations and legal
- Areas of development and further partnership development (incl. interactive exercise with the auditory)

Elena Adusei, Distribution Director Russia & CIS cluster Customer & Logistics Services EMEA, **Johnson & Johnson**

NEW MARKET INSIGHTS AND INDUSTRY SOLUTIONS

15.15

New PCM Pre-conditioning Methods for Reliable, Deterministic and Optimal Performance in a Total Quality System

- Modern passive thermal transport container: using high performance insulation and PCM materials
- Key to optimal shipment performance: How you can ensure accurate preconditioning of the PCM components
- Preconditioning procedure - easy to handle, reliable and auditable - possible solutions

Fabian Eschenbach, Manager Thermal Packaging, **Va-q-tec**

15.30 **Networking Break**

CLOSING KEYNOTE SESSIONS

16.00 **The Regulator's Perspective: GDP Inspections in Austria**

- Impact and challenges of the new GDP guideline for companies and inspectors in Austria
- The quality management system and the role of the responsible person in wholesalers (e.g. returned medicinal products, outsourced activities, etc.)
- Best/worst practices seen at inspections

Dr. Verena Plattner, Head GDP/GMP Inspections National, **Austrian Agency for Health and Food Safety (AGES)**

16.30 **The Regulator's Perspective - Cold Chain Transportation of Finished Product Within the United Kingdom**

- An inspector's perspective of the impact of the new GDP Guidelines on wholesaling and transportation
- Most common issues seen at inspections
- MHRA GDP expectations

Terry Madigan, GDP Inspector, Inspectorate, Enforcement and Standards Division, **MHRA**

17.00 **LEADING MINDS DISCUSSION: Strategic Logistics Partnerships: Building Trust, Streamlined Processes and Lower Risk Supply Chains**

Part I – What Pharma Needs

- Sharing common stories working with 'lead logistics providers'
- Deciding your strategy: how much control are you wiling to outsource?
- Collaborating with internal supply chain partners to ensure a thorough understanding and agreement of risk
- Dissemination of cold chain information from regional and international colleagues
- Meeting new EU GDP requirements for outsourcing

Part II – Execution of the Strategy with Partners

- The control of subcontractors, airlines, active container vendors, security and custom agents – who's managing what
- Contingency plans: reducing risk related to natural disaster and planning for delays
- Partnerships that manage and implement a quality supply chain security program

Panellists:
Zvonimir Majic PhD., Head of Quality Assurance EU Logistics, **Teva**
Maria D'Orazio, Head of Cold Chain Logistics, **Novartis**

17.40 **Chair's closing remarks and end of conference**