IQPC
International Quality & Productivity Center

> Very interesting and good package to increase knowledge and understanding of the cool chain management.
> Luc de Visscher, Distribution and Customer Service Manager, Sanofi Pasteur MSD

Special Feature:
Benchmark Case Study from the Fast Moving Consumer Goods Industry on "Opportunities to Measure & Improve Purchasing Performance"

2nd Global Symposium

COOLCHAIN

Temperature Controlled Europe 2008

Managing Internal & External Partners

Two Day Conference **8th - 9th September 2008** | Post-Conference Workshops **10th September 2008** | Mövenpick, Berlin, Germany

Latest Trends and Industry Case Studies from Global Players such as:

- **Genzyme,** UK
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- **Michigan State University - School of Packaging,** USA
- **Carrymed Pharma & Transport GmbH,** Austria
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- **WHO,** Switzerland
- **Schering Plough,** Belgium & The Netherlands
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- Discover how to draw-up and compile a **Service Level Agreement** from a **contractual** and **operational QA** point of view in order to effectively manage the quality aspects of drug manufacturing and controls
- Understand where the duties of each partner within the temperature controlled supply chain lie by accurately defining **accountability & liability**
- Learn how to improve contractor and supplier relationships through **collaborative partnering**
- Identify new trends and future challenges in **ambient temperature control** during transportation
- Optimise your **transport** and **distribution practice** through improved **purchasing** and **warehousing**

Highlight:

Dr. Ümit Kartoglu,
Technical Officer,
WHO, Switzerland

"Update from the Task Force on Pharmaceutical Cold Chain Formed at Last Years Conference"

Choose from 4 Interactive Workshops:

A Making Distribution a Priority through Effective Distribution Management and Streamlining Distribution Channels

C Quality Agreements – How to Make Sure that Contracts and Operations Fit

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Speaker Faculty

Elina Aine graduated from Tampere University of Technology with a Master of Science in Industrial Engineering and Management, with a major in Logistics and a minor in Industrial Management and Production. She joined Santen Oy, a Japanese owned Pharmaceutical company for ophthalmics. In her present function as Project Manager in Materials Management she is responsible for projects such as developing logistics processes between Japan and Finland; creating logistics process for product launches; sales and operations planning synchronisation; transportation management centralisation and risk management of procurement. Previously as Project Manager in Production she was responsible for projects such as decreasing setup and line clearance times in packaging operations; creating a new model to address need for more flexible human resources; the development of internal logistics processes; and developing more efficient internal documentation processes.

Tibor Both studied Chemical Enginieering at the Technical University in Budapest and has further educational training in Industrial Process Control, Foreign Trade and Marketing Management. For the past 22 years he has been working for Biogal Pharmaceutical Works (now Teva Pharmaceutical Works PLC.) API Division holding several positions as Engineer, Head of Ion-exchange Plant, Project-Leader and Product Manager. In his present function as Manager of Customer Service and Logistics Department, he is responsible for the organization of the foreign and domestic sales, transaction business and supply agreements, coordinating drug substances supplies as well as giving technical and scientific information to customers. He is also the co-owner of two Inventions and several Innovations.

Stefan Brinke studied Industrial Engineering at the Technische Hochschule in Darmstadt. For the past 14 years he has been working for Mars in purchasing and was responsible for Purchasing of Packaging Material, Equipment and Services and of Logistics Services for Germany, Benelux, France, Austria, Switzerland, Italy & Greece.

Jason Cameron, Head of Materials Management EMEA, Genzym, UK

Chris van Dam has 20 years experience in the Logistics environment in both operational and engineering functions. Since 2007 he is in charge of the International Distribution Center of Schering Plough, situated in Belgium, from which more than 100 countries are supplied by air, sea and road, under temperature controlled conditions. Chris is a member of several committees in charge of training programs for logistics personnel as well as working groups initiated by the Belgian Government to determine the long term strategy for Supply Chain initiatives in general.

Rudolf Eitler held several management positions in international companies mainly covering supply chain and logistics functions after finishing studies at the Wirtschaftsuniversität Vienna (International trade). Since 2000 he holds the position of a logistics manager for Europe for Baxter AG. He successfully implemented a transport and warehousing system for human plasma and set up a European Logistics Center for Baxter AG in Vienna by integrating third party logistics service providers. Rudolf has a broad experience in international cool chain logistics from bulk to sample shipments. Educated on Six-Sigma-Green-Belt-level Rudolf is acting as an independent consultant for different industries.

Klaus Gritschneder holds a degree in Communication Studies for Economics and Market and Advertising Psychology from the Ludwig-Maximilians-University in Munich. He started his professional carrier as a journalist for radio and television and then turned to public relations and consulting. For the past 10 years he has been working for the pharmaceutical industry. He is co-founder of the Europa Apotheek Venlo, and responsible for IT, public and political relations.

Jochen Heinzel started his career with F. Hoffmann-La Roche AG in Switzerland in 1995 after he studied Pharmaceutical Engineering at the University of Applied Sciences in Albstadt-Sigmaringen. After eight years experience in production as Head of the Antibiotics Packaging Department he moved into the Quality Assurance Supply Chain where he worked as a QA manager. Since 2003 he leads the group QA Distribution & 3rd Party Warehousing which was established in order to assure adherence to quality standards in the worldwide distribution as well as in warehousing at 3rd parties. Jochen Heinzel is member of Roche's Global Expert Team on Temperature Controlled Supply Chain as subject matter expert.

Dr. Ümit Kartoğlu is a scientist at the World Health Organization, Department of Immunization, Vaccines and Biologicals, Quality, Safety and Standards team. He is responsible for prequalification of all devices and equipment used in immunization services. Dr Kartoğlu also coordinates the work of Global Training Network on Vaccine Quality. Prior to his WHO work, Dr Kartoğlu worked with UNICEF as health officer in Central Asian Republics and Kazakhstan Area Office and as health coordinator for Operation Lifeline Sudan based in Kenya. Earlier he was Associate Professor in Public Health at the Institute of Pediatrics of Istanbul University and also held positions as permanent advisor in Public Health to the Ministry of Health in Turkey, and worked in different positions in rural health delivery system for 10 years. Dr Kartoğlu has 45 professional publications in public health including seven books/manuals targeting primary health care professionals used as teaching materials, and received two international research awards in research design and communication.

Peter Kralinger is Managing Director of Carrymed Pharma & Transport GmbH., the first licensed pharma company providing international transport of temperature sensitive pharmaceuticals. Before he was in charge of global transportation for all manufacturing sites in Europe of a large manfacturer of the pharmaceutical industry. All products were temperature sensitive and required cold chain transportation. The analysis of ten of thousands of shipments led to the development of an innovative approach towards cold chain management. He has more than 25 years experience in Engineering and Project Management and spent 17 years within the pharmaceutical industry. He was one of the founding members of the Pharma Logistics Forum, a platform for experts from the pharma industry striving for best practices in transportation.

Dr. Thomas Lenhard is pharmacist and chemist, and obtained his PhD in Pharmaceutical Chemistry at the University of Heidelberg. In 1986 he joined the department of Quality Control for Development Products of one of the Sanofi-Aventis predecessor companies. From here he moved to various managerial positions within the local and global quality control, quality assurance and supply chain. After having introduced the company wide material master data management approach he moved to his current position in October 2005 as Head of Quality Distribution Platform Frankfurt within the Sanofi-Aventis Deutschland GmbH. This function includes the nomination and legal responsibility as Qualified Person for the site Distribution Platform Frankfurt. Amongst others the functional responsibility covers all GDP regulations including quality assurance of transport related aspects.

Frank Meijerink started working for Organon (now Schering Plough) in 1996 as Transport Manager after working for a logistics service provider at Amsterdam airport for 10 years. In this role he was responsible for the worldwide distribution out of the Organon headoffice in Oss. Since March 2008 he is Senior Buyer Transport at the Procurement Department and in this function is responsible for projects related to commodity Transportation.

Dr. Paolo Ragusa is an italian born supply chain expert who studied Management Engineering at the Politecnico di Milano and in Spain, speaks different languages and, in his more than decennial experience at BASF, Fresenius Medical Care and Basilea Pharmaceutica, gained international exposure by holding several challenging roles mainly in Europe. He focused his knowledge and activities on the improvement of the supply chain organization through the redesign of the logistics infrastructure, the reorganization under tax savings potentials, the development of supply chain planning tools and ERP systems, the development of partnerships with customers, suppliers and contract manufacturers. He is currently responsible for the set up of the global supply chain and distribution organisation at Basilea Pharmaceutica.

Prof. Paul Singh graduated from Punjab University in India with a B.Sc. in Mechanical Engineering and an M.Sc. in Packaging. He did his Ph.D. in the Department of Agricultural Engineering at Michigan State University USA, during which time he was also an instructor at the School of Packaging. After graduation he soon advanced to Assistant Professor, Director and then full Professor at the School of Packaging, a position which he has held since 2000. Paul is a member of the Board of Directors of the International Association of Packaging Research Institutes and the International Safe Transit Association as well as being Chairman of the ASTM D10-Packaging Division 1 of the American Society of Testing and Materials International. His main research interests lie in the effect of shock, vibration and compression of product/package systems, damage reduction during transport and handling, as well as the environmental impact of protective packaging materials for transportation.

Dr. Jyrki Syväri, Pharmacist and Chemist, made his PhD Theses in Pharmaceutical Chemistry and his Diploma in Chemistry in Analytical Chemistry. He joined Schering AG in Berlin and led there a R&D Laboratory for the development of parenteral drugs. He left Schering AG to join Boehringer Ingelheim (corporate headquarters), where he became a Project Manager in Operations. Then he was responsible for the world-wide launches of new products, such as Metalyse and Spiriva. Now he is leading a group called "Launch and Special Supplies". In this function he is responsible for setting up supply chains for Boehringer Ingelheim's new products. New Supply Chain paradigms and concepts are also part of his responsibility. In this context new concepts for temperature controlled deliveries are being developed in his group.

Who will you meet?

Managers and Senior Managers from the Pharmaceutical Biotech and Veterinary Medicines Industries from the following departments:

- **Global Supply Chain Management**
- **Global Distribution Operations**
- **Global QA Operations**
- **Cool Chain Management**
- **Logistics**
- **Customer Service**

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2nd Global Symposium

COOLCHAIN

Temperature Controlled Europe 2008

CONFERENCE DAY ONE | Monday, 8th September 2008

8:30 Registration and Coffee

9:00 Welcome by Pharma IQ

9:05 Welcoming Address and Opening Remarks from the Chairman

9:15 **Update from the Task Force on Pharmaceutical Cold Chain Formed at Last Years Conference** HIGHLIGHT

- Industry collaboration for bringing minimum standards to the cold chain on a global level
  - Storage issues (main and sub stores)
  - Transport

Dr. Ümit Kartoglu,
Technical Officer,
WHO, Switzerland

Partnerships & Collaborations

10:00 **Managing the Supply Chain from a Contractual QA Point of View**

- How to set up Quality Agreements
- Who are the contract partners and what are the interfaces to be included
- What are the essential GMP/GDP-contents

Dr. Thomas Lenhard,
Head of Quality Distribution Platform Frankfurt / Qualified Person,
Sanofi Aventis, Germany

10:45 Networking and Morning Coffee

11:15 **Managing Logistics Service Providers from an Operational Quality Assurance Point of View**

- Quality Agreements - The baseline for surveillance of service providers on different stages along the supply chain
- Audits - The only way to discover secrets not seen on paper
- Deviation Management - As a starting point to initiate continuous improvement
- Training - To ensure all contracted topics are well understood in daily operations

Jochen Heinzel,
Head of QA Distribution & 3rd Party Warehousing,
F. Hoffmann-La Roche AG, Switzerland

12:00 **Accountability & Liability within the Temperature Controlled Supply Chain**

- Duties of concerned parties when transporting and distributing pharmaceuticals from manufacturer to patient
- Interdependencies of transport processes and protecting packaging systems
- Understanding and applying Incoterms 2000

Peter Kralinger,
Managing Director,
Carrymed Pharma & Transport GmbH, Austria

12:45 Networking luncheon

14:15 **Outsourcing Logistics Services in the Pharmaceutical Cool Chain**

- From strategy to operational realisation
- INPUT required from areas concerned in an outsourcing process (QA, Regulatory Affairs, Legal, HR, Training, Finance, IS, etc.)
- OUTPUT for areas concerned in an outsourcing project (HR, Legal, Customer Service, Finance, Transport, Warehousing, Order Fullfillment, Pick/Packing, QA, IS, etc.)
- Open book strategy with service providers
- Regular reviews
- Chances/opportunities for pushing quality levels through continuous process improvement
- Benefits (financial, service level, process stability)

Rudolf Eitler,
Manager Logistics Europe,
former Baxter Bioscience, Austria

15:00 **Importance of Excellent Cool Chain Supply Performance from a Sender's and Receiver's Point of View**

- Customer expectations
- GMP/GSP challenge
- Responsibilities of manufacturers and forwarders
- TIS system
- Bottle necks of the transportation process
- Solutions

Tibor Both,
Manager API Customer Service and Logistics,
Teva Pharmaceutical Works PLC., Hungary

15:30 Networking and Afternoon Refreshments

16:00 **Addressing Future Challenges in Ambient Temperature Control during Transportation**

- Proposal for setting harmonised industry standards
- Solving problems with partners
- Addressing challenges during cross-docking
- Temperature monitoring during distribution
- Future of temperature controlled transportation

Dr. Jyrki Syväri,
Head of Group Launch and Special Supply,
Boehringer Ingelheim GmbH, Germany

16:45 **Panel Discussion and Q&A Session** INTERACTIVE

"Unclogging the Pharma Supply Chain by Optimising Partnerships and Collaboration"
In this session you have the opportunity of putting your questions to a panel of speakers of the day

17:30 Closing remarks of the chairman and end of conference day one

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CONFERENCE DAY TWO | Tuesday, 9th September 2008

8:30 Registration and Coffee

9:00 Welcome by Pharma IQ

9:05 Welcoming Address and Opening Remarks from the Chairman

Warehousing, Transport & Distribution Practice

9:15 **FMCG-Purchasing Expertise - Opportunities to Measure & Improve Purchasing Performance**
- Goal-setting process for logistics costs
- How to measure purchasing performance within logistics?
- Tendering national distribution via online bidding - an opportunitiy to improve the purchasing performance

Stefan Brinke,
Logistics Buying Manager,
Mars GmbH, Germany

10:00 **The Way to Cost-Effective Temperature Controlled Transport**
- Choice of the mode of transport and control of the transport vehicle
- Choice of packing material
- Monitoring of temperature controlled goods

Chris van Dam,
Director International Distribution Centre,
Schering Plough, Belgium

Frank Meijerink,
Transport Manager,
Schering Plough, The Netherlands

11:00 Networking and Morning Coffee

11:30 **Setting up Temperature Controlled Ophthalmic Shipments Between two Consolidated Manufacturing Sites in Europe and Asia**
- Building a new logistics process – Balance between cost-efficiency, shipment quality and shipment reliability
- Impact of temperature controlled shipments on the lead time
- Transportation elements supporting the shipments to fulfil Japanese quality requirements: Reefers, shipment packaging and loading requirements
- Conducting a shipping study to confirm quality of shipment process and configuration
- Culture and language differences creating challenging environment for logistics

Elina Aine,
Project Manager,
Santen Oy, Finland

12:15 **Ongoing Asset and Facility Management within the Cool Supply Chain – Going to Direct Distribution**
- "Make to order" to reduce capital lock-up and unnecessary stocks, and avoid out of stock situations
- Synchronised order & supply processes
- Getting the right medication to the right patient at the right moment
- Direct distribution

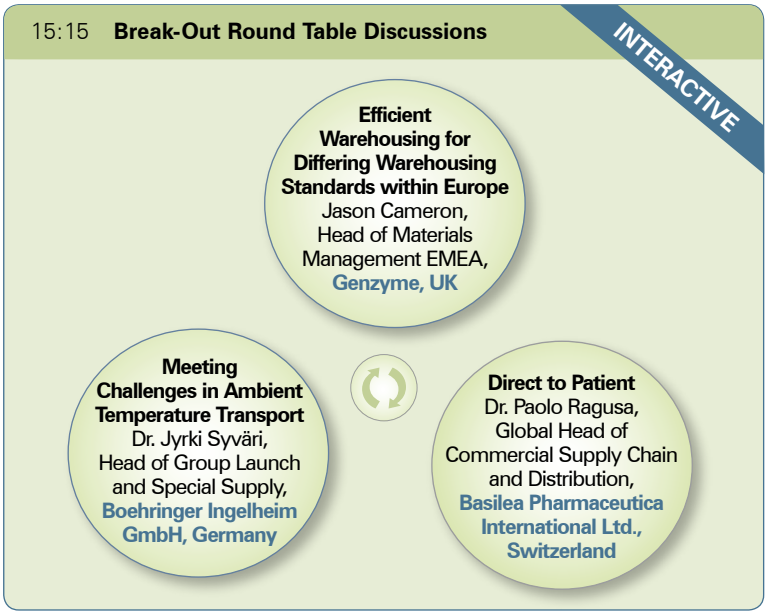
Jason Cameron,
Head of Materials Management EMEA,
Genzyme, UK

13:00 Networking luncheon

14:30 **The Logistics of a Mail Order Pharmacy**
- Tolerance margin = 0 in other words why controlling the logistics process is so important
- Temperature controlled drugs via mail order
- Just in time – keeping warehousing to a minimum

Klaus Gritschneder,
Member of the Board,
Europa Apotheek Venlo, NL

15:15 **Break-Out Round Table Discussions** INTERACTIVE



16:00 Networking and Afternoon Refreshments

16:30 **Measurement and Analysis of Vibration Data in Transport Vehicles and Creating Test Methods for Package Testing**
- Gain in-depth understanding of instrumentation used to measure vibration in truck, rail and air shipments
- Understand how to analyse vibration data to conduct accelerated tests
- Utilisation and development of lab based accelerated vibration tests
- Limitations of various test equipment on conducting "true replication"

Prof. Sher Paul Singh,
Professor,
Michigan State University - School of Packaging, USA

17:15 Closing remarks of the chairman and end of conference day two

Workshop A
9:00-12:30

Making Distribution a Priority through Effective Distribution Management and Streamlining Distribution Channels

Jason Cameron,
Head of Materials Management EMEA,
Genzyme, UK

The **quality of patient care** depends in part on your **pharmaceutical distribution** system, therefore getting the right medication to the right patient at the right moment is critical. But is the traditional model of pharmaceutical supply chain in Europe under threat as major pharmaceutical manufacturers in the UK attempt to change the way they distribute their products? The adoption of a **Direct-to-pharmacy** (DTP) model by some of the industry's most powerful players in the UK signifies a new trend that could spread across Europe. Join this interactive workshop and discover ways of **streamlining** your **distribution** channels and discuss:

- **Fast** and **cost-effectiv**e ways to streamline the distribution process
- **Tackling** the **pitfalls** of pharma distribution
- Is **direct-to-pharmacy** the new trend to follow and will it become the dominant method of drug distribution?

Workshop C
14:00-17:30

Quality Agreements – How to Make Sure that Contracts and Operations Fit

Thomas Lenhard,
Head of Quality Distribution Platform Frankfurt / Qualified Person,
Sanofi Aventis, D;

Jochen Heinzel,
Head of QA Distribution & 3rd Party Warehousing,
F. Hoffmann-La Roche AG, CH

Due to increased **outsourcing activities** in the Pharmaceutical and Biopharmaceutical industries, **Supplier Quality Agreements** play an ever important role in **ensuring drug quality** and **compliance** to current good manufacturing practice (cGMP). Quality agreements play a central role in defining the system and processes by which a client and vendor manage the quality aspects of drug manufacturing and controls through **collaborative partnering**. In order to be effective, a quality agreement and the supporting implementation process need to be **focused**, **clear** and **executable**. Attend this interactive workshop in order to learn how to **draw-up** and **compile a Quality Agreement** and be being given the operative means for **verification** purposes and **corrective measures** on the basis of a given case study by paying special attention to:

- Mode of **transport**
- **Distribution** practice
- Partners
- Pre-defined **QS-measures**

2nd Global Symposium

COOLCHAIN

Temperature Controlled Europe 2008

TWO DAY CONFERENCE 8th - 9th september 2008
PRECONFERENCE WORKSHOPS 10th September 2008
Mövenpick, Berlin, Germany

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Hear Top Level Industry Case Studies on:

- **Quality Agreements** from a contractual and operational QA point of view
- Accurately defining **accountability** and **liability** within the temperature controlled supply chain
- Improving contractor and supplier relationships through **collaborative partnering**
- Future challenges in **ambient temperature control**
- Optimising **transport** and **distribution practice** through improved purchasing and warehousing

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Please indicate choice of workshop on Monday, 10th September 2008
Workshop A: ☐ | Workshop C: ☐

A: Making Distribution a Priority through Effective Distribution Management and Streamlining Distribution Channels
C: Quality Agreements – How to Make Sure that Contracts and Operations Fit

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