

Seamless Pharmaceutical Cold Chain Distribution Conference

Maintaining Unadulterated Medicinal Products Through the Supply Chain

July 25-26, 2006

Sheraton Philadelphia City Center
Philadelphia, PA

"ACHIEVE A SEAMLESS COLD CHAIN
TO ENSURE PRODUCT SAFETY, INTEGRITY AND QUALITY
through appropriate controlling and monitoring
OF THE DISTRIBUTION CHAIN."



Minimize risk of adulterated temperature-sensitive products with best practice management tools, use of innovative technology and building robust relationships with key logistics partners.

Keynote Presenter:

Claudia Okeke

Associate Director Information
& Standards Development

United States Pharmacopeia (USP)

Gain Valuable Insight from:

- Incorporating RFID and related technologies for effective cold chain management
- Building strategies to monitor products through entire transportation system
- Leveraging regulatory agencies requirement to improve CCM
- Collecting data of product temperature to be inspected by FDA
- Effectively working with freight forwarders and third-party carriers

Book Online At:

www.marcusevansbb.com/coldchain

Featuring Case Studies from Leading Experts Including:

Ian Holloway

Senior Pharmaceutical Assessor,
Divisional Quality, Systems and Standards
Medicines and Healthcare Products
Regulatory Agency (MHRA)

Louis A. Coury, PhD

Manager,
Corporate Reference Standards Group
Manager, PR&D Bulk Analytical Testing Labs
Eli Lilly

Gregory S. Wallace

Chief, Vaccine Supply & Assurance Branch,
Immunization Services Division,
National Center for Immunization
and Respiratory Diseases
**Centers for Disease Control
and Prevention**

Kathryn Denholm

Quality & Validation Manager
FedEx Custom Critical, Inc.

Ryan Craft

Lab Manager
Westpak, Inc.

Mark Escobedo

Chief Technologist
Westpak, Inc.
**San Jose State University
College of Engineering –
Packaging Program**

Raymond Jenkins

Demand & Logistics Manager
Mayne Pharma USA

Dianne Heiler

Packaging Engineering Manager
Applied Biosystems

Barbara B. Zinck

Senior Director, Corporate Compliance
Cambrex Corporation

Sara Fletcher

Manufacturing Engineering Manager
Affymetrix

Gene Fedors

Vice President, Education Programs
RFID Technical Institute

Exhibitor Sponsor:

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7:30 Registration and Networking Breakfast

8:45 Welcome from Chair

9:00 Keynote Presentation

Leveraging Requirements of USP Guidelines on Storage and Shipping

- Understand changing expectations of manufacturer's responsibility across the supply chain
- Incorporating key aspects of regulatory requirements into company's standard operating procedures
- Tapping key personnel/departments to ensure comprehensive communication about critical components

Claudia Okeke

Associate Director Information & Standards Development

United States Pharmacopeia (USP)

9:45 Case Study

Meeting European Regulatory Expectations for Handling Temperature Sensitive Products

- Exercising control on Good Distribution Practices (GDP) to ensure safety of medicinal products
- Implementing quality and standards systems that meet EU compliance
- Building practices that incorporate different expectations from EU and US guidelines

Ian Holloway

Senior Pharmaceutical Assessor, Divisional Quality, Systems and Standards

Medicines and Healthcare products Regulatory Agency (MHRA)

10:30 Morning Refreshments and Networking Opportunity

10:45 Case Study

Effective Vaccine Cold Chain Management

- Outlining CDC Guidelines for:
 - Temperature requirements for vaccine storage and shipment
 - Proper use of refrigerators and freezers for vaccine storage
 - Appropriate temperature monitoring practices
- Implementing effective procedures for the careful storage and handling of vaccines

Gregory S. Wallace

Chief, Vaccine Supply & Assurance Branch
Immunization Services Division
National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

11:30 Case Study

Aligning the Manufacturing Processes with External Expectations

- Best practices in maintaining ambient temperatures and handling reagents
- Translating good internal manufacturing practices to external cold chain management with logistics partners
- Effectively building meaningful data for quality control and compliance
- Analyzing processes and looking for ways to improve and streamline costs

Sara Fletcher

Manufacturing Engineering Manager

Affymetrix

12:15 Lunch for All Delegates and Speakers

1:30 Case Study

Building Cost Effective Transportation Strategies to Strengthen Distribution System

- Practical approaches to reducing costs related to packaging and transportation
- Selection of logistics and distribution partners that fit product profile
- Implementing effective shipping guidelines to maintain service levels

Dianne Heiler

Packaging Engineering Manager

Applied Biosystems

2:15 Case Study

Fast Tracking Global Transportation of Products

- Reducing import transit time of products
- Discussion on refrigerated transportation, US Customs and other pertinent regulations
- Reverse logistics and handling customer returns and short-dated products
- Reducing inventory costs

Raymond Jenkins

Demand & Logistics Manager

Mayne Pharma USA

3:00 Case Study

Ensuring the Integrity of Reference Standards in a Global Pharmaceutical Business

- Types of reference standards and customer requirements
- Temperature conditions during transit and dealing with excursions
- Cycle times for shipments to various locations and sources of variability

Louis A. Coury, PhD

Manager, Corporate Reference Standards Group
Manager, PR&D Bulk Analytical Testing Labs

Eli Lilly

3:45 Afternoon Refreshments and Networking Opportunity

4:00 Case Study

Incorporating RFID and Related Technologies for Effective Cold Chain Management

- Understanding the synergies between radio frequency identification, sensors, and wireless networks
- Utilizing RFID active tagging for Cold Chain process improvement
- Challenges, benefits and approaches to RFID-enabled Cold Chain solutions
- RFID case studies: projects in progress today, capabilities planned for tomorrow

Gene Fedors

Vice President, Education Programs

RFID Technical Institute

4:45 Closing Remarks from the Chairperson and End of Day One

Sponsorship Opportunities:

A limited amount of exhibition space is available at the conference. Sponsorship opportunities covering luncheon, evening functions, and documentation also exist. For further details, contact Chip Heflin, General Manager, Sponsorship at 312 894 6382 or email: chiph@marcusevansch.com.

Technology Tools, Logistic Partners

- 8:00 Registration and Networking Breakfast
- 8:30 Opening Remarks from the Chair
- 8:45 Case Study

Quality Agreements: A Pre-Cooperative Agreement to Corroborate What We Said and Avoid He Said – She Said

- Understand how critical it is to clarify and document responsibilities and expectations between contract giver and contract acceptor regarding quality aspects of the outsourced activity
- Using a Quality Agreement to clarify the functional aspects of a business relationship
- Defining responsibilities of quality, regulatory and production personnel within each company and improving communication
- Learn key elements of international regulatory requirements for a quality agreement to avoid surprises and misunderstandings

Barbara B. Zinck
Senior Director, Corporate Compliance
Cambrex Corporation

- 9:30 Case Study

Leveraging Third Party Services to Optimize Cold Chain Distribution

- Capitalizing on the logistics services and expertise of 3PLs
- Integrating partners into your existing cold chain distribution network
- Avoiding common hurdles in delivery of service; Building lasting relationships with 3PLs

Kathryn Denholm
Quality & Validation Manager
FedEx Custom Critical, Inc.

- 10:15 Meet and Greet Networking Break
- 10:30 Case Study

Packaging Technology and Testing Products

- Procuring the right equipment for valid testing and setting the procedures
- Identifying the variety of thermal mass products
- Reporting of results
- Developing thermal models for various packaging systems

Ryan Craft
Lab Manager
Westpak, Inc.
Mark Escobedo
Chief Technologist
Westpak, Inc.
San Jose State University
College of Engineering – Packaging Program

- 11:15 Case Study

Building Quality Validation and Qualification Systems

- Differentiating between validation and qualification as applied to the manufacturing, storage and distribution processes
- How to set critical parameters for processes and procedures, equipment and facilities to form the basis for good cold chain management practices
- How to develop efficient on-going assessment of systems

- 12:00 Lunch for All Delegates and Speakers
- 1:00 Case Study

Other Partners to Consider in Building a Seamless Network

- How pharmacies can impact the success of cold chain management
- Where do hospitals and clinics fit into network efficiency
- Strengthening the communication channel between manufacturers, distributors and frontline healthcare partners

- 1:45 Closing Remarks from the Chair and End of Conference

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