A Message from the Program Chair

Dear Colleague:

Temperature-controlled pharmaceuticals, bio-pharmaceuticals and vaccines are increasing in number to address many of the unmet needs to help the patient. The handling, storing and distribution of these products on a world-wide basis require reaching for global scientific consensus for patient safety. The industry, their partners and service providers must cooperate to ensure that the quality, integrity, potency and efficacy of pharmaceuticals are not compromised during the various handlings until they reach the patient.

In its sixth consecutive year, the 2011 PDA Pharmaceutical Cold Chain Management Conference will focus on the various challenges, solutions and case studies regarding integrated supply chain management and Good Distribution Practices (GDP). Representatives from the Food and Drug Administration (FDA), United States Pharmacopeia (USP), industry and cold chain solution providers will discuss, review and debate many of these cold chain issues as they pertain to importation, nationalization and distribution. Experts with industry experience from Latin America will share their regulatory objectives, key compliance activities and solutions to the common problems that shippers experience in their efforts to import, export and distribute pharmaceutical products in this region of the world.

We have designed a session on stability budget as a means of protecting drug quality in the distribution environment. The presenters will describe and justify the studies using scientific data and rationale necessary to determine an appropriate stability budget for a drug substance or drug product. This will also include a status update regarding the publication of the PDA's PCCIG Task Team Guidance.

With the overwhelming number (and volume) of GDP regulations and guidelines from both industry and MOH’s, a special session will address what are “they” asking us to do? This session will identify the 30+ GDP world-wide regulations, guidelines and position papers on the Good Distribution Practices (GDPs) and will outline/summarize a clear understanding of what is expected. Topics to be discussed include temperature management, supply chain integrity and information control/sharing.

Smart shippers and the reusability of containers will demonstrate some environmentally friendly solutions. A first time review of the recommended guidance by the PCCIG’s Active Packaging Systems Task Team will be presented.

The two-day conference will conclude with invited guests from the FDA presenting on Good Distribution Practices (GDP), Good Importation Practices (GIP) and Labeling Requirements.

On behalf of the Program Planning Committee I extend a personal invitation to you and your colleagues to join us on March 1-2, 2011 in Bethesda, Maryland, for what is promising to be an informative, stimulating and engaging conference. Optimize your travel dollars and extend your stay in Bethesda for the PDA Training and Research Institute (TRI) course, Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing and Transport Systems, March 3-4, 2011.

With kind regards,

Rafik H. Bishara, PhD
Leader, PDA Pharmaceutical Cold Chain Interest Group (PCCIG) and Chair, 2011 PDA Pharmaceutical Cold Chain Management Conference Program Planning Committee

Rafik Bishara, PhD
PDA Pharmaceutical Cold Chain Interest Group (PCCIG)

Program Planning Committee

Chair
Rafik Bishara, PhD
PDA Pharmaceutical Cold Chain Interest Group (PCCIG)

Jason E. Brown
PDA

Chris Chandler
Department of Veterans Affairs
Great Lakes CMOP

Edward Church
ISTA

Bob Dana
PDA

James Dowden
Genentech, Inc

Jean-Pierre Emond, PhD
University of South Florida Polytechnic

Paul Harber
Eli Lilly and Company

Claude Joliceur
McKesson Canada

Karl Kussow
FedEx Custom Critical

Jeff Seely
JLS Distribution Packaging, LLC

Bob Seevers, PhD
Eli Lilly and Company

Edward Smith, PhD
Packaging Sciences Resources

Dave Ulrich
Abbott Laboratories

www.pda.org/coldchain2011
Tuesday, March 1, 2010

7:00 a.m. - 8:00 a.m.
Continental Breakfast

7:00 a.m. - 5:15 p.m.
Registration Open

8:00 a.m. - 8:05 a.m.
Welcome and Opening Remarks
Bob Dana, Senior Vice President of Regulatory Affairs and TRI, PDA

8:05 a.m. - 10:00 a.m.
Opening Plenary Session: Introduction and Regulatory Update
Moderator: Rafik Bishara, PhD, Leader, PDA Pharmaceutical Cold Chain Interest Group (PCCIG) and Chair, 2011 PDA Pharmaceutical Cold Chain Management Conference Program Planning Committee
An overview of the various activities and projects by the PCCIG Steering Committee and membership of the Interest Group will be presented.

8:05 a.m. - 8:30 a.m.
Cold Chain Update
Rafik Bishara, PhD, Leader, PDA Pharmaceutical Cold Chain Interest Group (PCCIG)

8:30 a.m. - 9:00 a.m.
USP General Chapters: Current and Future Directions
Anthony DeStefano, Vice President, General Chapters, USP

9:00 a.m. - 9:30 a.m.
The Whole Import Including Temperature Control
FDA Speaker Invited

9:30 a.m. - 10:00 a.m.
Q&A

9:45 a.m. - 6:30 p.m.
Exhibit Area Open

10:00 a.m. - 10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. - 11:05 a.m.
Brazilian/ANVISA Import Issues
Emily Pereira, CMP Analyst, Abbott Laboratories Brazil

11:05 a.m. - 11:25 a.m.
Improving Compliance and Increasing the Speed of the Import Process
Elaine Araújo Menezes, Quality Operations Coordinator, Abbott Laboratories Brazil

11:25 a.m. - 11:45 a.m.
Response to Argentina Law Current Status
Sonia Seino, Latin America Regulatory Affairs Manager, Eli Lilly and Company, Argentina (Invited)

11:45 a.m. - 12:15 p.m.
Q&A

12:15 p.m. - 1:30 p.m.
Lunch

1:30 p.m. - 3:00 p.m.
Plenary Session 3: Global Comparison of Cold Chain/GDP Regulations
Moderator: David Ulrich, QA Director, Distribution, Abbott Laboratories
With the overwhelming number (and volume) of Good Distribution Practice (GDP) regulations and guidelines from both industry and MOH’s, what are “they” asking us to do? This session will identify the 30+ GDP world-wide regulations, guidelines and position papers on the GDPs and will outline/summarize a clear understanding of what “they” are looking for us to do. This session will display a guideline or regulation, and then give a brief summary of the high level point of that particular guideline/regulation. It will focus on the broader GDPs – not just cold chain (topics will be temperature management, supply chain integrity and information control/sharing).

1:30 p.m. - 2:30 p.m.
Global Comparison of Cold Chain/GDP Regulations
David Ulrich, QA Director, Distribution, Abbott Laboratories

2:30 p.m. - 3:00 p.m.
Panel Discussion

3:00 p.m. - 3:45 p.m.
Refreshment Break in Exhibit Area

3:45 p.m. - 5:15 p.m.
Plenary Session 4: A Stability Budget as a Means of Protecting Drug Quality in the Distribution Environment
Moderator: Bob Seevers, PhD, Principle Regulatory Scientist, Regulatory Affairs, CMC, Eli Lilly and Company
The purpose of this session is to describe and justify the studies using scientific data and rationale necessary to determine an appropriate stability budget for a drug substance or drug product. A stability budget considers the results of long term, accelerated, freeze/thaw and temperature cycling studies to determine the amount of time out of storage that a drug may experience without any significant risk to its quality. Firms have used the idea of a stability budget to assign permissible time out of storage for packaging and labeling operations.
Tuesday, March 1 - Wednesday, March 2 Agenda (continued)

For refrigerated drug products for some time. This concept has been expanded by the PDA Task Force into a draft document to include storage and distribution as well. The document is intended to complement existing guidance on stability studies and maintaining the quality of pharmaceuticals during distribution.

3:45 p.m. - 4:15 p.m.
Overview
Bob Seavers, PhD, Principle Regulatory Scientist, Regulatory Affairs, CMC, Eli Lilly and Company

4:15 p.m. - 4:45 p.m.
Stability Budget
Paul Harber, Associate Engineering Consultant, Eli Lilly and Company

10:15 a.m. - 10:45 a.m.
Packaging School Perspective on Good Cold Chain Management Practices (GCCMP)
Industry Speaker Invited

10:45 a.m. - 11:15 a.m.
Multidisciplinary Approach in Cold Chain Management Research
Jean-Pierre Emond, PhD, Dean and Research Professor, College of Technology & Innovation, University of South Florida Polytechnic

11:15 a.m. - 11:45 a.m.
Q&A

11:45 a.m. - 1:00 p.m.
Lunch on your own

1:00 p.m. - 1:20 p.m.
Status Report and Overview of PDA's PCCIG Active Systems Team
Edward J. Smith, PhD, Principal Consultant, Packaging Science Resources

1:20 p.m. - 1:45 p.m.
Qualification of Walk-In Cold Rooms/Refrigerators/Freezers
John Bratz, Professional Services Life Science Manager, Sensitech, Inc.

1:45 p.m. - 2:10 p.m.
Qualification of Temperature-Controlled Active Unit Load Devices
Todd DeVore, Director of Product Development and Engineering, AcuTemp Thermal Systems

2:10 p.m. - 2:35 p.m.
Qualification of Temperature-Controlled Trucks and Trailers Used to Transport Pharmaceutical Materials
Gerry Marasigan, Director, Validation & Compliance, SNC Lavalin Pharma

2:35 p.m. - 2:45 p.m.
Q&A

2:45 p.m. - 3:30 p.m.
Refreshment Break in Exhibit Area

Wednesday, March 2, 2011

7:00 a.m. - 8:00 a.m.
Continental Breakfast
7:00 a.m. - 3:30 p.m.
Registration Open

8:00 a.m. - 9:30 a.m.
Plenary Session 5: Smart and Reusable Containers for Good Cold Chain Management
Moderator: MaryAnn Gribbin, Director of Logistics, Johnson and Johnson
Innovative concepts of smart containers and review of reusable shipping containers will be presented.

8:00 a.m. - 8:30 a.m.
Taking Temperature Monitoring to the Next Level with Smart Containers
Christian Bogatu, PhD, Director, Kirsen Global Security

8:30 a.m. - 9:00 a.m.
Reusable Containers in Supply Chain of Temperature-Sensitive Pharmaceuticals
Geoffrey Glauser, Managing Consultant, KW Tunnell

9:00 a.m. - 9:30 a.m.
Q&A

9:15 a.m. - 3:30 p.m.
Exhibit Area Open

9:30 a.m. - 10:15 a.m.
Refreshment Break in Exhibit Area

10:15 a.m. - 10:45 a.m.
Packaging School Perspective on Good Cold Chain Management Practices (GCCMP)
Industry Speaker Invited

10:45 a.m. - 11:15 a.m.
Multidisciplinary Approach in Cold Chain Management Research
Jean-Pierre Emond, PhD, Dean and Research Professor, College of Technology & Innovation, University of South Florida Polytechnic

11:15 a.m. - 11:45 a.m.
Q&A

11:45 a.m. - 1:00 p.m.
Lunch on your own
Wednesday, March 2 Agenda (continued)

3:30 p.m. - 5:00 p.m.
Plenary Session 8: Compliance with GDP, GIP and Labeling Requirements
Moderator: Bob Dana, Senior Vice President of Regulatory Affairs and TRI, PDA
The closing session of this conference will explore issues surrounding controls for importation of pharmaceuticals. FDA has recently implemented the PREDICT (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting) program to assist import entry reviewers in targeting high-risk shipments for examination, as well as expediting clearance of lower-risk cargo. An FDA representative has been invited to discuss the programs objectives and share the results of the implementation, including successes and future challenges. Finally, various schemes have been proposed to identify drug products and track their history in the distribution chain. The session will conclude with a review of the GS1 product identification scheme (specifically GTIN and GLN) for pharmaceuticals, from the perspective of this session’s presenters.

3:30 p.m. - 4:00 p.m.
FDA Importation Requirements
FDA Speaker Invited
4:00 p.m. - 4:30 p.m.
GS1 Overview (GTIN and GLN Implementation)
FDA Speaker Invited
4:30 p.m. - 5:00 p.m.
Q&A

5:00 p.m.
Closing Remarks and Adjournment
Rafik Bishara, PhD, Leader, PDA Pharmaceutical Cold Chain Interest Group (PCCIG)

Learning Objectives:
At the completion of this program, participants will be able to:
• Describe the current global regulatory environment for pharmaceutical materials that require temperature-controlled transport and storage
• Maintain effective relations with global trade organizations
• Increase efficiency of cold chain control systems through understanding of new technology and the transportation environment
• Establish and control the migration process from cold chain management to Good Distribution Practices (GDP)
• Develop the position guidance for the PCCIG priority projects addressing cold chain gaps
• Integrate supply chain management from cold chain to GDP
• Mitigate risk in cold chain good distribution practices

Who Should Attend:
Departments
Operations | Regulatory Affairs | Manufacturing
Transportation | Packaging | Quality Assurance/Control
Logistics and Solution/Service Providers
Job Function
Manufacture of temperature-sensitive materials | Transportation of temperature-sensitive materials | Packaging engineers
Stability coordinators | Supply chain | Logistics
Cold chain service providers

PDA Training and Research Institute Course

PDA Training and Research Institute Course: Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing and Transport Systems
In conjunction with the 2011 PDA Pharmaceutical Cold Chain Management Conference, the PDA Training and Research Institute (PDA TRI) is offering a course related to the latest technologies, learning resources and regulatory expectations in regards to cold chain management. The course will be held at the PDA Training and Research Institute in Bethesda, Maryland; a short ride from the Bethesda North Marriott Hotel on the Red Line of the Washington, DC Metro System.

4350 East West Highway, Suite 150
Bethesda, MD 20814

Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing and Transport Systems
March 3-4, 2011 | 8:30 a.m. - 4:00 p.m.
PDA #122 | ACPE #0116-0000-11-122-L04-P | 1.2 CEUs
Type of Activity: Knowledge, Application

This course will provide you with an introduction to Good Distribution Practices (GDPs) and includes a review of USP Chapter 1079 as well as cold chain regulations and documents from Europe, including the UK and Ireland. You will learn the contents of PDA Technical Report No. 39, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment and International Air Transport Association (IATA) Chapter 17 compared to earlier developed guidance such as the International Safe Transit Association (ISTA) 5B.
PDA Training and Research Institute Course (continued)

Topics to be included:

• The critical steps to collecting data from the distribution environment to be used for development of realistic ambient profiles for focused simulation testing
• Standard organization activities related to cold chain package testing
• Development of a validation master plan for temperature-sensitive pharmaceutical distribution packaging

An introduction to GDP through industry consensus practices for thermal package development and qualification will be presented and discussed along with a case study that will address how to deal with temperature excursions from trip monitoring data.

Who Should Attend
Managers and staff in pharmaceutical manufacturing who need an awareness of distribution, packaging and cold chain compliance will benefit most from this course. This includes those working in quality assurance, distribution and packaging engineering departments, regulatory management and field compliance inspectors.

Learning Objectives
Upon completion of this course, you will be able to:

• Describe the global practices and regulatory requirements for cold chain distribution compliance
• Explain guidance and regulatory requirements of the manufacturer for distribution and packaging of products
• Identify critical steps to development of profiles for simulation testing
• Describe the distribution environment

Instructors
Rafik Bishara, PhD, PDA Pharmaceutical Cold Chain Interest Group (PCCIG)
Tom Pringle, Industry Advisor

Recommended Reading
PDA Technical Report No. 39, Revised 2007, Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment

The PDA Training and Research Institute is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Education Units (CEUs) following the successful completion of an accredited course and submission of the provided evaluations forms. Statements of Credit for CEUs earned will be mailed within four to six weeks of the event.

General Information

Three Ways to Register
1. Click www.pda.org/coldchain2011
2. Fax +1 (301) 986-1093
3. Mail PDA Global Headquarters
   Bethesda Towers
   4350 East West Highway, Suite 150
   Bethesda, MD 20814 USA

Conference Venue
Marriott Bethesda North Hotel and Conference Center
5701 Marinelli Road
Bethesda, MD 20852
Phone: +1 (301) 822-9200
Website: www.marriott.com/wasbn

The group rate is $209 single/double occupancy and $264 double occupancy, plus applicable state and local taxes. Book your reservation by January 31, 2011 to receive the PDA rate.

Course Venue
The PDA TRI course accompanying the conference will be held at the PDA Training and Research Institute:
4350 East West Highway, Suite 150
Bethesda, MD 20814

Conference Registration Hours
Tuesday, March 1: 7:00 a.m. – 5:15 p.m.
Wednesday, March 2: 7:00 a.m. – 3:30 p.m.

Course Registration Hours
Registration begins at 7:30 a.m. on Thursday, March 3 and Friday, March 4 at the PDA Training and Research Institute.
On-site registrations will be accepted Tuesday, March 1 and Wednesday, March 2 at the Bethesda North Marriott Hotel.

Dress/Attire
Business casual attire is recommended for the 2011 PDA Pharmaceutical Cold Chain Management Conference. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

Special Requirements
If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to day@pda.org.

Contact Information
For conference inquiries:
Jason E. Brown, Senior Programs Manager
Tel: +1 (301) 656-5900 ext. 131 | E-mail: brown@pda.org

For registration inquiries:
Patresa Day, Manager, Registration and Customer Accounts
Tel: +1 (301) 656-5900 ext. 115 | E-mail: day@pda.org

PDA TRI course inquiries:
Stephanie Ko, Sr. Manager, Lecture Education
Tel: +1 (301) 656-5900 ext. 151 | E-mail: ko@pda.org

Exhibition/Sponsorship inquiries:
David Hall, Vice President, Sales
Tel: +1 (301) 760-7373 | Cell: +1 (240) 688-4405 | E-mail: hall@pda.org
1 Contact Information

PDA Membership Number:

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☐ Substituting for

[Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the additional fee.]

2 Conference Registration | March 1-2, 2011. Please check appropriate fee (US$)

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* For this nonmember type, online registration is not available and must be faxed in.

Please note: In order to receive the prevailing rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

Register 4 people from the same organization and same site (at the same time) and receive the 5th registration free. Other discounts cannot be applied.

3 Course Registration | March 3-4, 2010.

Please check appropriate fee (US$)

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4 Payment Options  All cards are charged in US$. 

☐ By Credit Card - Clearly indicate account number and expiration date and billing address. 

Total amount $ 

Please bill my: ☐ American Express ☐ MasterCard ☐ VISA ☐ Credit Card Guarantee Only 

Account Number Exp. Date Signature 

Name (exactly as it appears on card) 

Billing address 

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Wire Transfer Payments: If you require wire transfer, please contact Patresa Day at day@pda.org

CONTRIBUTION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please submit payment for the prevailing rate. Please be advised that if payment or written cancellation notice is not received by January 3, 2011, your credit card will be charged the prevailing rate. SUBSTITUTIONS: If you are unable to attend, substitutions can be made at any time, including on site at the prevailing rate. If you are a nonmember substituting for a member, you will be required to pay the difference for the nonmember fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. REFUNDS: Refund requests must be in writing and faxed to +1 (301) 986-1093. Emails and phone messages are not accepted. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee at the on-site registration rate if your cancellation has not been received in writing on or before January 3, 2011. Refunds for Conference/Events: If your written request in received on or before January 3, 2011, you will receive a full refund minus a $200 processing fee. After that time, no refunds or credit requests will be approved. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. Refund for Courses: If your written request is received on or before January 3, 2011, you will receive a full refund less the $200 processing fee. EVENT CANCELLATION: PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA is not responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at info@pda.org or +1 (301) 986-5000. PHOTO RELEASE: By registering for the 2011 PDA Pharmaceutical Cold Chain Management Conference, I authorize PDA the right to photograph me and to use the photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership.

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PDA Federal Tax I.D. #52-1906152
Sponsorship and Exhibit Opportunities are Available!

High impact, cost-effective sponsorship and exhibition packages are available for the 2011 PDA Pharmaceutical Cold Chain Management Conference. Gain on-site exposure and connect with industry experts from manufacturing, operations, quality assurance, packaging, logistics and supply chain as well as representatives from regulatory agencies.

This year's agenda provides ample time for exhibitors to make new contacts and network with attendees who will be seeking solutions and guidance on the handling and distribution of temperature-sensitive pharmaceuticals. Exhibit at this conference to gain business relationships, connect with key players in the industry and improve your sales.

In addition, comprehensive sponsorship packages will provide your company the opportunity to strengthen brand image, increase visibility and reinforce its commitment to the pharmaceutical cold chain management arena. Sponsorships are also available for lanyards, USBs, notepads, pens, refreshment breaks, lunch and the networking reception.

For more information about exhibit and sponsorship opportunities, please contact:

David Hall
Vice President, Sales
Direct: +1 (301) 760-7373  |  Cell: +1 (240) 688-4405
E-mail: hall@pda.org

www.pda.org/coldchain2011