



Connecting People, Science and Regulation®

A PDA European Conference

# Pharmaceutical Cold Chain Management

Important Factors to Consider

**17-18 October 2007**  
**Berlin, Germany**

Conference, Exhibition 17-18 October 2007  
Training Course 15-16 October 2007

[www.pda.org/europe](http://www.pda.org/europe)

**Save before  
31 August 07!**

# Pharmaceutical Cold Chain Management

## Important Factors to Consider

### Overview

Participants in the 2007 European PDA Cold Chain Management Conference will have the opportunity to join colleagues and experts from around the world to learn how the current risk-based regulatory environment is affecting what pharmaceutical professionals need to do to ensure product and patient safety when dealing with temperature – sensitive pharmaceuticals. Members of the PDA Pharmaceutical Cold Chain Interest Group (PCCIG), Cold Chain Committee (C3), and Pharma Logistics Forum (PLF) will examine the newly revised PDA Technical Report No. 39, Cold Chain Guidance for Medicinal Products: Maintaining the Quality of temperature-sensitive Medicinal Products through the Transportation Environment. This will include the harmonization effort and the future plans of cooperation. Seven plenary sessions will focus on all relevant topics for those who are involved with cold chain and temperature – controlled management practices. By attending this year's cold chain conference you will learn from those who have "put science and technology into practice for Good Cold Chain Management Solutions." Rafik H. Bishara, *PhD, Chair, PCCIG and Conference Chair*

### Who Should Attend

#### Specialty Areas

Pharmaceutical/Biopharmaceutical Manufacturing  
Transportation and Logistics  
Cold Storage  
Wholesale/Retail Pharmacy  
Cold Chain Management and Solutions  
Cold Supply Chain

#### Departments

Regulatory Affairs  
Development  
Quality Assurance/ Quality Control  
Manufacturing  
Engineering  
Logistics

#### Job Function

Stability  
Packaging  
Quality  
Transportation of Temperature-Sensitive Materials  
Supply Chain

### Venue and Hotel

#### Hotel Meliá Berlin

Friedrichstrasse 103, D-10117 Berlin  
Tel: +49 (0) 30 – 20 60 790-0  
Fax: +49 (0) 30 – 20 60 790-444  
Email: andrea.palme@solmelia.com  
www.solmelia.com

**Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.**

### Planning Committee

Rafik H. Bishara, *PhD, Chair, PCCIG and Conference Chair*  
Claude Ammann, *Apoxis SA, Switzerland*  
Detlef Dichte, *Lilly, Germany*  
Shirley Ann Feld, *Sanofi Aventis, Germany*

Frederike Graeper, *PDA Europe*

Søren Kåre Nielsen, *Novo Nordisk, Denmark*

Georg Roessling, *PhD, PDA Europe*

Hugo Wegewijs, *Johnson & Johnson, Switzerland*

### Contact

**For conference information, please contact:**

PDA Europe  
Adalbertstr. 9  
16548 Glienicke/ Berlin, Germany  
Tel: +49 (0) 33056- 23 77 10  
Fax: +49 (0) 33056- 23 77 77  
Email: info-europe@pda.org

### Exhibition

Exhibition and Sponsorship Opportunities are available. PDA meetings and conferences are a great opportunity for your company to gain on-site exposure in front of highly-qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Exhibit at PDA events and let your company's products or services become a valuable tool or resource for our attendees.

**For more information, please contact:**

Astrid Guenther, *Marketing Manager, PDA Europe*  
Tel: +49 (0) 33056-23 77 11  
Email: guenther@pda.org

### PDA Training Courses

The Training Course will take place on 15 – 16 of October 2007 at the conference hotel.

**Title: "Good Cold Chain Management Training"**

**Part 1: Global Regulations and Standards**

**Part 2: The Development and Testing of Cold Chain Packages and Transport Systems**

[www.pda.org/europe](http://www.pda.org/europe)

# Program-at-a-Glance

## Wednesday, 17 October 2007

07:30 - 17:00 Registration and Welcome Coffee

### SESSION 1: Introduction / Overview

Moderator: Rafik Bishara, PhD

09:00 – 09:15 Opening and Welcome

Georg Roessling, PhD, PDA Europe  
Rafik Bishara, PhD, Chair, PCCIG and  
Conference Chair

09:15 – 09:45 PCCIG – Global Activities

Rafik Bishara, PhD, Chair, PCCIG

09:45 – 10:15 C3 – Global Activities

Hugo Wegewijs, Chair, C3, Johnson & Johnson

10:15 – 10:45 PLF – Global Activities

Shirley Ann Feld, M.Sc, PLF Core Team,  
Sanofi Aventis

10:45 – 11:00 Q & A

11:00 – 11:30 Coffee Break & Exhibition

### SESSION 2: Global Stability for Cold Chain Management

Moderator: Claude Ammann

11:30 – 12:00 A Mathematical Approach to Assessing  
Temperature – Excursions in Temperature-  
Controlled Chains

Claude Ammann, Apoxis SA

12:00 – 12:30 Risk Management Approach to Shipping and  
Distribution of Temperature-Sensitive Products

Gwyn Murdoch, Lilly

12:30 – 12:45 Q & A

12:45 – 13:45 Lunch

### SESSION 3: Packaging for Transport

Moderator: Prof. Jean-Pierre Emond

13:45 – 14:15 Fundamentals of Thermal Protection Design  
for Temperature-Sensitive Products –  
Shipping Container

Prof. Jean-Pierre Emond, University of Florida

14:15 – 14:45 The Needs for Enhanced Testing Standards for  
Temperature-Sensitive Parcel Packaging

Don Pagel, Kodiak Thermal Technologies, Inc.

14:45 – 15:00 Q & A

15:00 – 15:30 Coffee Break & Exhibition

### SESSION 4: Global Regulatory Requirements

Moderator & Panel Discussion Leader: Rafik Bishara, PhD

15:30 – 16:00 Ensuring the Optimal Potency of Vaccine by  
Evaluation of Stability Data – a Case Study

Umit Kartoglu, PhD, WHO

16:00 – 16:30 Title to be announced

Speaker from USP

16:30 – 17:00 Speaker and Title to be announced

17:00 – 17:30 Panel Discussion:  
Cold Chain Topics in Europe: Regulatory  
Requirements and Harmonization Challenges/  
Industry Perspective: A Wish List from the  
Industry

18:30 Networking Event (incl. Dinner)

## Thursday, 18 October 2007

### SESSION 5: Validation/Qualification & Risk Management

Moderator: Søren Kåre Nielsen

08:15 – 08:30 Review of Day 1

Rafik Bishara, PhD

08:30 – 09:00 Transport Qualification of Sea Shipments

Thomas Lenhard, Sanofi-Aventis

09:00 – 09:30 Interlab Variability for Packaging Qualification

Robert Willemse, Topa Verpakking B.V.

09:30 – 10:00 Validation Procedures and Standards in  
Evaluating Insulation Containers

Nicola Spiggelkoetter, Absolute Cold GmbH

10:00 – 10:30 Performance Quality and Safety (PQS): A  
New System for Specifying, Testing and Pre-  
Qualifying Products for Use in Immunization  
Programmes – Cold Chain Implementation

Andrew Garnett, WHO Temporary Adviser

10:30 – 10:45 Q & A

10:45 – 11:15 Coffee Break & Exhibition

### SESSION 6: Distribution and Transportation

Moderator: Shirley Ann Feld

11:15 – 11:45 Temperature Data Evaluation and the  
Continuous Improvement of the Cold Chain

Johan Nordberg, Environtainer Inc.

11:45 – 12:15 CCQI – Standard-Efficient Benchmarking  
in Supply Chain Quality for Perishables and  
Temperatures-Sensitive Products

Hanspeter Raschle, Germanische Lloyd

12:15 – 12:45 Impact of Transportation and Distribution  
on Environment

Tony Wright, Exelsius-Cold Chain  
Management Consultancy

12:45 – 13:00 Q & A

13:00 – 14:00 Lunch

### SESSION 7: Partners in Supply Chain

Moderator: Kevin O'Donnell

14:00 – 14:30 An Overview of IATA's Perishable Goods Regu-  
lations, Chapter 17 – Air Transport Logistics  
for Temperature-Sensitive Healthcare Products

Kevin O'Donnell, Tegrant Corporation,  
ThermoSafe Brands

14:30 – 15:00 Understanding Temperature Variation "Know  
What You Are Monitoring"

Jeff Leshuk, Sensitech

15:00 – 15:30 Best Practices in Temperature Control Trans-  
portation

Joe Childs, FedEx

15:30 – 16:00 Cold Chain Monitoring with PDF-Logger – No  
Software Needed at Destination

Alois Bischof, Elpro-Buchs AG

16:00 – 16:15 Q & A

16:15 – 16:30 Closing Remarks

Georg Roessling, PhD, PDA Europe  
Rafik Bishara, PhD, Chair, PCCIG

# Registration Form



# Pharmaceutical Cold Chain Management

17-18 October 2007, Berlin, Germany

Conference, Exhibition 17-18 October, Training Course 15- 16 October

## 3 WAYS TO REGISTER

**FAX: +49 33056 23 77 77 ONLINE: www.pda.org/europe**

**MAIL: PDA Europe, Adalbertstr. 9, 16548 Glienicke/Berlin, Germany**

### 1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr.  Ms.  Dr.  PDA Member  Nonmember

Name (Last, First, MI) \_\_\_\_\_

Job Title \_\_\_\_\_

Department \_\_\_\_\_ Company \_\_\_\_\_

Mailing Address \_\_\_\_\_

City \_\_\_\_\_ Postal Code \_\_\_\_\_

Country \_\_\_\_\_ Email \_\_\_\_\_

Business Phone \_\_\_\_\_ Fax \_\_\_\_\_

Substituting for \_\_\_\_\_  
(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

### 2 Conference Registration

#### All Prices in Euro

	By 31 Aug 2007	After 31 Aug 2007
PDA Member	<input type="checkbox"/> 1395	<input type="checkbox"/> 1495
Nonmember*	<input type="checkbox"/> 1590	<input type="checkbox"/> 1690
Regulation	<input type="checkbox"/> 570	<input type="checkbox"/> 615
Academic**	<input type="checkbox"/> 570	<input type="checkbox"/> 615
Student**	<input type="checkbox"/> 215	<input type="checkbox"/> 230

\* Nonmember registration fee includes a one-year PDA membership. If you do not wish to join PDA and receive the benefits of membership, please check here (same rate applies).

\*\* Must be a PDA member to receive this rate.

\*\*\* includes two days

### 3 Course Registration

#### PDA#122-1: Good Cold Chain Management Training

	By 31 Aug 2007	After 31 Aug 2007
<b>Training Course only</b>		
PDA Member***	<input type="checkbox"/>	<input type="checkbox"/> 1595
Nonmember*, ***	<input type="checkbox"/>	<input type="checkbox"/> 1790
<b>Conference + Training Course</b> (Please fax or mail registration form to receive this special offer)		
PDA Member	<input type="checkbox"/> 2790	<input type="checkbox"/> 2890
Nonmember*	<input type="checkbox"/> 2990	<input type="checkbox"/> 3090

### 4 Payment Options

**By Credit Card** (American Express, MasterCard, VISA, Diners Club) clearly indicating account number and expiration date.

**Please bill my:**  American Express  MasterCard  VISA  Diners Club \*

Total Amount \_\_\_\_\_

Card Number \_\_\_\_\_ Exp. Date \_\_\_\_\_

Name (exactly as it appears on card) \_\_\_\_\_

Signature \_\_\_\_\_

**\*All cards are charged in Euro. PDA Europe VAT I.D.: DE254459362**

#### By Bank Transfer

**Beneficiary:** PDA Europe gGmbH

**Account No:** 09 228 735 00

**IBAN:** DE73 1007 0024 0922 8735 00

**BIC (SWIFT-Code):** DEUTDE33HAN

**Bank Address:** Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

**Invoice**  Please mark here to request an invoice from PDA. You are not considered registered for a PDA event until payment is received and a confirmation letter is issued by PDA. Should you attend an event without a formal confirmation or receipt of payment you will be required to provide a credit card as guarantee of payment.

**CONFIRMATION:** 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 have received an invoice please be advised that you are not a confirmed registrant. You are not confirmed until payment has been received. Please submit payment for 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 non-member substituting for a member, you will be required to pay the difference of the non-member 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 PDA at +49 (33056) 23 77 77 (emails are not accepted).** If your written request is received on or before **17 September 2007**, you will receive a full refund minus a Euro 150 handling fee. After that time, no refund or credit requests will be approved. 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 **3 October 2007**. 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 by **22 September 2007**, you will receive a full refund less a Euro 150 processing fee. After that time, no refund or credit requests will be approved. **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 as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at **info-europe@pda.org** or fax to **+49 (33056) 23 77 77**.

**PDA USE ONLY**

Date: \_\_\_\_\_ Check: \_\_\_\_\_ Amount: \_\_\_\_\_ Account: \_\_\_\_\_