



Connecting People, Science and RegulationSM



PDA Global PAT Conference

Unlocking the Knowledge in Your Process

**MAY 22-23, 2007 | BETHESDA, MARYLAND
CONFERENCE | EXHIBITION**

Register by May 7 and Save!

www.pda.org/pat

A Message from the Program Planning Committee Chair

Dear Colleague:

In 2005, PDA initiated a task force dedicated to advancing the science and knowledge of Process Analytical Technology (PAT), and determined to develop a shared learning experience for industry, regulatory authorities and the pharmacopoeias on the implementation of PAT platforms within development and manufacturing.



On behalf of the Program Planning Committee, I am pleased to invite you to the **PDA Global PAT Conference: Unlocking the Knowledge In Your Process**. Industry leaders will come together at this conference to share case studies on actual PAT implementation programs across the parenteral, biotech and oral dosage form product life cycles. Additionally, session moderators will address such issues as the challenges incorporating information technology into PAT and strategies for PAT program development and implementation.

PDA recognizes the challenges that growing companies face with regard to executing PAT. As such, we will dedicate a special session to discuss solutions for small and medium-sized companies. Audience participation is encouraged to discuss strategies and experiences in implementing PAT within the context of available resources.

This conference is a tremendous opportunity to benchmark recent successes in PAT implementation across our industry. We look forward to seeing you at the **PDA Global PAT Conference** in May!

Sincerely,



Michael J. Miller, Senior Research Fellow, *Eli Lilly and Company*
PDA Global PAT Conference Program Planning Committee Chair

2007 PDA Program Planning Committee

Michael Miller, PhD, Chair
Eli Lilly and Company

Duncan Low
Amgen, Inc.

Mohammed Barkat
Draxis Pharma

Walter Morris
PDA

Jason E. Brown
PDA

Michiel Rook
Millipore, BioPharmaceutical

Rick Cooley
Dionex Corporation

John Shabushnig, PhD
Pfizer Inc

Volker Eck, PhD
PDA Europe

Harald Stahl, PhD
Niro Pharma Systems

Michael Lennick
Global Biologics Supply Chain, LLC

Who Should Attend

Departments

- Regulatory Affairs
- QA/QC
- Manufacturing Operations
- Process Development
- Component and Material Suppliers

Job Function

- Process Development
- Consulting
- Biopharmaceutical Manufacturing
- Biopharmaceutical Quality Management

This conference will be held in conjunction with
**Quality by Design for Biopharmaceuticals:
Concepts and Implementation—A PDA Workshop,**
May 21-22, 2007. For more information visit
www.pda.org/qbd.

PDA Global PAT Conference

Agenda

Tuesday, May 22, 2007

12:00 p.m. – 2:45 p.m.

Registration Open

2:00 p.m. – 6:30 p.m.

Exhibit Area Open

1:00 p.m. – 1:15 p.m.

Welcome and Opening Remarks

Michael Miller, PhD, Senior Research Fellow, *Eli Lilly and Company*, PDA Global PAT Conference Program Planning Committee Chair

1:15 p.m. – 2:15 p.m.

Opening Plenary Session: The Case for PAT

Moderator: Michael Miller, PhD, Senior Research Fellow, *Eli Lilly and Company*

Implementing PAT is challenging, both financially and scientifically, but the results can be highly rewarding. For example, PAT can play an integral role in Quality by Design (QbD), which in turn can reap financial rewards and enable regulatory flexibility to companies.

■ 1:15 p.m. – 2:00 p.m.

Keynote Presentation: The QbD to PAT Link

FDA Speaker Invited

■ 2:00 p.m. – 2:15 p.m.

Question and Answer

Panel Discussion with Opening Plenary Session Speakers

2:15 p.m. – 2:45 p.m.

Refreshment Break in Exhibit Area

■ 2:45 p.m. – 5:30 p.m.

Plenary Session 2: Case Studies PAT in Process Development

Moderator: Michiel Rook, European Access Services Manager, *Millipore BioPharmaceutical Division*

Case studies of real-life examples of the application of PAT during process development across various product platforms will be presented.

■ 2:45 p.m. – 3:30 p.m.

Process Mass Spectrometry as a Scale-up Tool Supporting Quality by Design (QbD)

Jacob Remacle, Senior Technician, Development Engineering, *Eli Lilly and Company*

■ 3:30 – 4:15 p.m.

Advances of PAT-Technologies for Cycle Development of Freeze Drying Process

Georg Frinke, Mechanical Engineering/R&D, *GEA Lyophil GmBH*

■ 4:15 p.m. – 5:00 p.m.

Use of Near-Infrared Spectroscopy in Process Characterization of Dry Granulation Properties by Roller Compaction

David Reed, Research Advisor, *Eli Lilly and Company*

■ 5:00 p.m. – 5:30 p.m.

Question and Answer

Panel Discussion with Plenary Session 2 Speakers

5:30 p.m. – 6:30 p.m.

Networking Reception in Exhibit Area

Wednesday, May 23, 2007

7:00 a.m. – 3:15 p.m.

Registration Open

10:15 a.m. – 3:15 p.m.

Exhibit Area Open

7:00 a.m. – 8:00 a.m.

Continental Breakfast

8:00 a.m. – 10:15 a.m.

Plenary Session 3: Case Studies-PAT in Manufacturing

Moderator: Michael Lennick, Assistant Director, Process Sciences, *Global Biologics Supply Chain, LLC*

Several firms have begun using PAT in their manufacturing operations. Real-life case studies will address how PAT can be implemented across various product platforms, including Aseptic Processing, Blending and Purification.

■ 8:00 a.m. – 8:45 a.m.

Use of On-Line Blender Monitoring During Development, Process Scale-Up and Technical Transfer

Aaron Garrett, Senior Research Scientist- Group Leader, *Eli Lilly and Company*

■ 8:45 a.m. – 9:30 a.m.

PAT in Aseptic Processing

Richard Saunders, PhD, Vice President, Pharmaceutical Development, *Wyeth* (Invited)

Agenda *(continued)*

■ 9:30 a.m. – 10:15 a.m.

The Implementation of Process Analytical Technology to Monitor and Control the Purification Process at a Bulk Insulin Site

Joseph Zajac, Associate Senior Analytical Chemist,
Eli Lilly and Company

10:15 a.m. – 10:45 a.m.

Refreshment Break in Exhibit Area

10:45 a.m. – 12:30 p.m.

Plenary Session 3: Case Studies: PAT in Manufacturing (continued)

Moderator: Michael Lennick, Assistant Director, Process Sciences, *Global Biologics Supply Chain, LLC*

Several firms have begun using PAT in their manufacturing operations. Real-life case studies will address using at-line HPCL for optimal outcome and product quality in spray drying.

■ 10:45 a.m. – 11:30 a.m.

Using At-Line HPLC to Reduce Assay Costs and Increase Process Capacity

Charles Kettler, Senior Research Scientist,
Eli Lilly and Company

■ 11:30 a.m. – 12:15 p.m.

A Risk-Based Approach to Product Quality in Spray Drying

Henrik Schwartzbach, Pharma Division Process Technologist,
Niro A/S

■ 12:15 a.m. – 12:30 p.m.

Question and Answer

Panel Discussion with Plenary Session 3 Speakers

12:30 p.m. – 1:30 p.m.

Lunch in Exhibit Area

1:30 p.m. – 2:45 p.m.

Plenary Session 4: Meeting the PAT/IT Challenge

Session Moderator: Rick Cooley, Manager, Process Analytics Center of Excellence, *Dionex Corporation*

A large component of any PAT project is the link to information technology. Presentations will offer solutions to the PAT/IT challenge.

■ 1:30 p.m. – 2:00 p.m.

Implementation of Computer Systems Validation and Part II in PAT

Johnny Guerra, Industry Consultant, *Guerra Consulting Group, Inc.*

■ 2:00 p.m. – 2:30 p.m.

Plug and Play PAT: Common PAT Software

Velumani Pillai, Senior Manager/Team Leader,
Global Manufacturing, Pfizer Inc

■ 2:30 p.m. – 2:45 p.m.

Question and Answer

Panel Discussion with Plenary Session 4 Speakers

2:45 p.m. – 3:15 p.m.

Refreshment Break in Exhibit Area

3:15 p.m. – 4:45 p.m.

Plenary Session 5: Strategizing for PAT Program Development and Implementation

Moderator: Mohammed Barkat, Vice President, *Draxis Pharma*

Companies need to develop their PAT implementation strategies within the context of available resources. This session will explore options and viable strategies for companies of all sizes. Audience participation will be encouraged.

■ 3:15 p.m. – 3:45 p.m.

Implementing Process Analytical Technology in a Growing Company

Andrew Lange, Senior Scientist, Analytical Development,
Vertex Pharmaceuticals Incorporated

■ 3:45 p.m. – 4:15 p.m.

High-Shear Granulation and Bi-Layer Tableting: Process Optimization and Process Understanding-Case Study

Jason Kamm, Tunnell Managing Consultant,
Tunnell Consulting, Inc.

■ 4:15 p.m. – 4:45 p.m.

Open Discussion

4:45 – 5:00 p.m.

Closing Remarks and Adjournment

PDA Global PAT Conference

Continuing Education



PDA is approved by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Following full attendance, completion and submission of the appropriate evaluation form(s), certificates will be mailed within four to six weeks of the event. Continuing Education Units (CEUs) will be awarded as follows:

PDA Global PAT Conference

1.1 CEUs for 1.5 days/Full Conference
ACPE # 116-000-07-057-L04

Learning Objectives

At the end of this conference, participants will be able to:

- Define PAT's role in a broader QbD program
- Identify how pharmaceutical and biotech manufacturers are assessing, designing and implementing PAT
- Compare various PAT alternatives for different product/process applications
- Summarize the value and return on investment when implementing PAT
- Evaluate options for incorporating PAT into existing IT infrastructure and validating PAT IT systems

On-Demand Web Seminar: Online Liquid Chromatography as a PAT in Biotech Process Development

Speaker: Rick E. Cooley, Manager, *Process Analytics Center for Excellence, Dionex Corporation and Eli Lilly and Company* (retired)

This presentation will include examples of online Liquid Chromatography applications in biopharmaceutical processes involving the production and purification of peptide and protein products. The examples will be used to explain how online Liquid Chromatography has been utilized for monitoring to increase process knowledge as an enabling technology for process automation and control to increase process efficiency and reduce process variability.

For more information on this and other on-demand web seminars, visit www.pda.org/ondemand.

About PDA

Connecting Science, People and RegulationSM

The Parenteral Drug Association (PDA) is a nonprofit international organization and a leading global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community. PDA is committed to developing sound, practical technical information and resources to advance science and regulation through the expertise of its more than 10,000 members worldwide. More information about PDA is available at www.pda.org.

Exhibition and Sponsorship Opportunities 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. Thousands attend PDA events to stay abreast of new regulations - and the science and technology to comply.

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:

Cindy Tabb

Manager, Sales
Tel: +1 (301) 656-5900 ext. 222
Fax: +1 (301) 986-0296
Email: tabb@pda.org

Recommended Resources

You may find the following publications to be excellent references and supplements to the topics discussed during the PDA Global PAT Conference. To order visit www.pda.org/bookstore.

Laboratory Validation: A Practitioners' Guide

Edited by **Jeanne Moldenhauer, PhD**
Item no. 17201 – **Save 20%**

Risk Assessment and Risk Management in the Pharmaceutical Industry Clear and Simple

Author: **James L. Vesper**
Item no. 17219

Successfully Validating ERP Systems (and Other Large, Configurable Applications)

Author: **David Stokes**
Item no. 17245

The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance

Author: **Siegfried Schmitt**
Item no. 17234

Encyclopedia of Rapid Microbiological Methods, Volume I, Volume II and Volume III

Edited by **Michael J. Miller, PhD**
Item no. 17252 – **Buy All 3 Volumes and Save 20%**

Environmental Monitoring – Volume I, Volume II and Protocol CD

Edited by **Jeanne Moldenhauer, PhD**
Item no. 17239

Registration Fees (US\$)

March 12-May 7

PDA Member:	\$ 1,050
Nonmember*:	\$ 1,450
Government:	\$ 430
Health Authority**:	\$ 430
Student**:	\$ 160

After May 7

PDA Member:	\$ 1,150
Nonmember*:	\$ 1,550
Government:	\$ 470
Health Authority**:	\$ 470
Student**:	\$ 175

* Registration fee includes a one-year PDA membership.

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

Three Ways to Register

1. Click www.pda.org/pat
2. Fax +1 (301) 986-1093
3. Mail **PDA Global Headquarters**
Bethesda Towers
4350 East-West Highway
Suite 200
Bethesda, MD 20814 USA

Venue

Hyatt Regency Bethesda

One Bethesda Metro Center (7400 Wisconsin Avenue)

Bethesda, MD 20814

Tel: +1 (301) 657-1234

Fax: +1 (301) 657-6453

Website: www.bethesda.hyatt.com

The group rate is \$225 single/double occupancy, plus 12% state and local taxes. Book your reservation by April 22, 2007 to receive the PDA room rate.

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

Registration Hours

(Badge pick-up and on-site registration)


Tuesday, May 22: 12:00 p.m. – 2:45 p.m.

Wednesday, May 23: 7:30 a.m. – 3:15 p.m.

Dress/Attire

Business casual attire is recommended for the PDA Global PAT Conference. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.

Special Requirements

 Business casual attire is recommended for the PDA Global PAT Conference. Since the temperature in meeting rooms tends to be cool, please bring a jacket or sweater for your comfort.



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PDA Global Headquarters

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