



2006 PDA BIENNIAL TRAINING CONFERENCE

TRAINING ... A WINNING STRATEGY



Connecting People, Science and RegulationSM

Philadelphia, Pennsylvania

Conference: May 8-10
TRI Training Courses: May 11-12
Exhibition: May 8-9



REGISTER BY MARCH 7TH (FOR CONFERENCE) AND
MARCH 11TH (FOR COURSES) FOR EARLY BIRD DISCOUNTS

www.pda.org/training2006

2006 PDA BIENNIAL TRAINING CONFERENCE



A MESSAGE FROM THE PROGRAM CHAIR



Joanne Cochran
Program
Committee Chair

Dear Colleague,

The program planning committee is pleased to invite you and your staff to attend the *2006 PDA Biennial Training Conference*, May 8-10, 2006 in Philadelphia, Pennsylvania. We've listened to your comments from the successful 2004 conference and have enhanced this year's program to fit your needs from start to finish. There will be 35 concurrent sessions split into five distinct tracks: **Regulatory Updates, Technical Training, Training Management, Professional Trainers and Theory and Design.** These sessions, plus plenty of networking opportunities, give you an ideal forum to learn from the experiences and successes of your peers.

The Trainers' Choice Awards — where *you* pick the winners — will be featured again this year. Learn about some of the best training programs that have been developed by your colleagues, and get take-home tips from the developers to implement at your organization.

The plenary session will be given by Steven Smith of Rummler-Brache. This session will provide tools and models for you to analyze and measure your training processes, as well as evaluate the performance results your training is designed to deliver.

Attend the FDA sessions to get up-to-the-minute news on current thinking and have your questions answered by the experts.

We have a great location, a dynamic program and wonderful opportunities to make "Training a Winning Strategy." The only other thing we need is you!

See you in May in Philadelphia.



JWC Training Associates
Program Committee Chair

2006 PDA Training Conference Program Committee

Joanne Cochran
JWC Training Associates
Program Committee Chair

David Fant
David Fant Associates
Program Committee Vice Chair

Matthew I. Anderson
Cardinal Health

Wanda Neal Ballard
PDA

Jason E. Brown
PDA

Paul B. Conlon
PBC Consulting LLC

Yvonne Cotti
Schering-Plough

Lina V. Divitt
Chiron Corporation

Gary German
FDA

Thomas G. Nimmer
Global GMP Consulting, Inc.

William F. O'Connor
Bristol-Myers Squibb
Medical Imaging, Inc.

Rick H. Rogers
Independent Consultant

Gail Sherman
PDA Training and Research
Institute

Robin O. Wachter
Eli Lilly & Co.

Thomas W. Wilkin, EdD
New York City College of
Technology

Joyce S. Winters
Wyeth Pharmaceuticals

Vendor Liaison
James Vesper
LearningPlus, Inc.

2006 PDA Trainers' Choice Awards

Back by popular demand! The prestigious *Trainer's Choice Awards* will be presented to trainers, by their peers, for outstanding achievement in design, development and delivery of cGMP and technical training programs or materials in the following categories:

- Best Multimedia Presentation
- Best Classroom Training Manual
- Best e-Learning Program/Web Page
- Best Experiential/Interactive Training

Learn about some of the best training programs that have been developed by your colleagues, and get take-home tips from the developers to implement at your organization.

Finalists will display their materials at the conference. Conference attendees will choose the winners who will be announced on the final day of the conference, May 10, 2006.

CONFERENCE HIGHLIGHTS

How quickly can your staff adapt to new challenges in an industry as complex and dynamic as pharmaceuticals?

As the pharmaceutical environment becomes more and more challenging, it is critical for organizations to have well-trained workforces to implement new technologies effectively and efficiently. This year's PDA Biennial Training Conference will feature 35 concurrent sessions covering five learning tracks aimed at helping you develop a winning strategy for success:



Regulatory Updates – Better understand current regulatory requirements and leverage proven strategies to meet training and business needs



Technical Training – Learn new techniques, strategies and best practices to improve training performance



Training Management – Integrate training into your business strategy



Professional Trainers – Evaluate and improve trainer performance with results-focused processes and strategies



Theory and Design – Examine new instructional design techniques, strategies and current theories for developing training programs



Who Should Attend

- GXP Trainers
- Supervisors
- Training Professionals
- Training Managers
- Quality Personnel
- Technical Trainers

Learning Objectives:

- Improve the performance of your employees
- Present GXP training that engages your audience
- Inform your site of the latest regulatory requirements
- Apply the latest training trends and techniques

KEYNOTE SPEAKER: STEPHEN G. SMITH, SENIOR VICE PRESIDENT & MANAGING EXECUTIVE, RUMMLER-BRACHE

Interactive Workshop: Enhancing Training Effectiveness and Performance Results

With respect to GMP compliance training, you must wear different hats. As a training specialist, you are called upon to develop and deliver training that pertains to the regulations governing the manufacture of pharmaceutical products. As a performance consultant, you are called upon to achieve improved performance from the individual job performers you have trained. So, how do your training delivery and alternative interventions really affect the way employees do their jobs and achieve the desired outcome? This highly interactive session provides the tools and models you need to analyze and measure your training processes as well as evaluate the performance results your training is designed to deliver.

What You Will Learn

- A simple and repeatable approach to measure the performance of your training processes
- How to set metrics targets and goals for the training process to align performance with your corporate strategy for GMP compliance
- How to determine the effectiveness of your training through the use of the Human Performance System
- How to use feedback from performance results to continually improve your training processes

About The Speaker



Stephen G. Smith

Steven G. Smith has been the Senior Vice President and Managing Executive of the Rummler-Brache Group for the past several years, and provides the vision and direction of the Rummler-Brache performance management methodology, educational workshops and consulting services. He is a highly motivational, energetic speaker and an accomplished communicator. Prior to joining the Rummler-Brache Group, Smith's career focused on operations excellence in the automotive and high-tech industries. Smith has a BS in Business Administration and a MS in Operations Management.

SUNDAY, MAY 7, 2006

- 3:00 p.m. - 5:00 p.m.
Registration Open
- 5:00 p.m. - 6:00 p.m.
Meet and Greet Reception

MONDAY, MAY 8, 2006

- 7:00 a.m. - 4:30 p.m.
Registration Open
- 7:00 a.m. - 4:45 p.m.
Exhibit Area Open
- 7:00 a.m. - 8:00 a.m.
Continental Breakfast in Exhibit Area
- 7:00 a.m. - 8:00 a.m.
New Member Breakfast
- 8:00 a.m. - 9:15 a.m.
Welcome and Committee Plenary Session
 - **Opening Remarks and Conference Overview**
Joanne Cochran, *JWC Consulting*, 2006 Program Planning Committee Chair
 - **P1 – Plenary Session – “Training ... A Winning Strategy”**
2006 Program Planning Committee
- 9:15 a.m. - 10:15 a.m.
P2 – Plenary Session
Thomas D. Gardine, District Director, Philadelphia District, *FDA*
Charles M. Edwards, Investigator, *FDA*
- 10:15 a.m. - 11:15 a.m.
Refreshment Break & Demonstration/Display of Trainers’ Choice Finalists in Exhibit Area (Trainers’ Choice Display open from 10:15 a.m. - 4:45 p.m.)

- 11:15 a.m. - 12:30 p.m.
Concurrent Sessions



Julius Meisel, President,
Quality is Learned, Inc.

C1: Applications of Risk Management Methods in Pharmaceutical Manufacturing: What Trainers Need to Know

Using a combination of lecture, demonstration, focused questioning and interactive discussion, this session will address:

- The history and basic concepts of the science of risk analysis
- Common components of all risk management methods
- How and why the FDA and other regulatory agencies are applying risk management principles and methods to regulatory functions
- How risk management is likely to affect the future of quality systems and of pharmaceutical manufacturing in general



Maureen Jennings, Sr. Training Administrator,
3M Pharmaceuticals

C2: Operator Certification: Ensuring cGMP Compliance and Business Success

Nearly ten years ago, 3M implemented an operator certification program at their Northridge facility. This session will describe this process and how it identifies job requirements for every job in manufacturing; outlines specific steps to reach proficiency in these job requirements; and requires ongoing documented performance at the maximum proficiency level to provide confirmation that their employees are manufacturing a pure and unadulterated product.



Vivian Bringslimark, Senior Consultant,
Parexel Consulting

C3: A Curriculum Approach to GMP Training

Participants will receive a field tested model that organizes training program elements into a straightforward process flow. They will also collect a list of recommended tools for maintenance and continuous improvement of the program which yield measurable results.



Patricia Johnson, Principal,
Quality Systems & Training Resources, LLC

C4: Are you a Training Conference Commando?

Learn how to build relationships with fellow trainers/conference attendees that will help you accomplish goals back at the office in less time and using a smaller budget. Take away time saving strategies to keep resources readily available for future needs.



Vince Carlisi, Training Specialist, *Blood Systems*
Jill Drummond, Director, *Blood Systems*

C5: Got WOW! Getting Over the PowerPoint Blahs!

Learn how you can produce professional looking video training presentations with very little cost and almost no learning curve from the comfort of your office. The presenters will share their experience in creating dynamic interactive training programs formatted in streaming video media.

- 12:30 p.m. - 1:45 p.m.
Networking Luncheon

- 1:45 p.m. - 3:00 p.m.
Concurrent Sessions



Michelle Paganini, President,
Michelle Paganini & Associates

C6: FDA’s Quality Systems Approach to cGMP

This session will explore three key principles of the FDA’s guidance document Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations, 9/04 through interactive exercises and discussion — Management Responsibility, Corrective and Preventive Action (CAPA) and Statistical Techniques (as used in corrective action monitoring and trending). These three areas represent an opportunity to convey that the “c” in cGMP is a methodology that supports the management team’s ability to effectively use resources, prioritize issues and manage cost and quality.

The session will also include a debriefing of the training techniques used and a list of resources for further understanding the quality systems guideline requirements.

2006 PDA BIENNIAL TRAINING CONFERENCE AGENDA



Ines Cereijo, Professor,
UADE

C7: Proficiency Testing Program for the Pharmaceutical Industry

In order to produce consistently reliable data, a laboratory must implement an appropriate program of assurance and performance monitoring procedures. Proficiency testing is one of these procedures.

The pharmaceutical industry is beginning to recognize the need for proficiency testing to verify the ability of the laboratory to perform a method. This session will explore and clarify the fundamental nature of a proficiency testing program and its impact on the quality of laboratory results.



Eric Meier, PhD, President, Head Quality Management,
Pentaparm Ltd.

C8: Cost Effective Training For Small and Middle-Sized Pharmaceutical and Diagnostic Companies

Small and middle-sized companies have the same requirements as large companies for well educated and trained personnel but may not have the resources available. At this session receive practical information on developing a cost effective way to plan and implement training.



Edward Schwartz, Training Manager,
Corporate Compliance, *Amgen*

C9: Project Management for Trainers — Assuring On-Time and On-Budget Product Delivery

Using a series of project management tools, participants will have the opportunity to take one of their own projects and work through it.



Joanne Gallant, Development & Training Specialist,
Bristol Myers Squibb

C10: Designing Games for Use in GMP Training

This session will focus on the design and delivery of a totally interactive, participant driven training session. Participants will leave with a roadmap on how to design their own interactive activity.

■ 3:00 p.m. - 3:30 p.m.

Refreshment Break & Demonstration/Display of Trainers' Choice Finalists in Exhibit Area

■ 3:30 p.m. - 4:45 p.m.

Concurrent Sessions



Ron Midgett, PhD, Manager GMP Training,
Pliva Inc.

C11: GMP and Technical Training to Meet Compliance and Business Needs

This session focuses on a model that meets regulatory requirements while also meeting business needs. Attendees will have the opportunity to perform a gap analysis of their own training programs based on the model.



Niall Carolan, PhD, Training Manager,
Human Genome Sciences

C12: From R & D to Commercial Production: Impact on Training Requirements

Find out how Human Genome Sciences improved their operational performance by implementing a technical training program that includes unit training manuals and a structured manual certification process.

In developing this program, Human Genome Sciences aimed to:

- Ensure that their staff was adequately trained on SOPs requiring competency training
- Train their staff beyond the SOPs to become Subject Matter Experts (SMEs).



Robert Knapp, Director of Product Services, *Wyeth BioPharma*
Peter Dango, Technical Training Specialist, *Wyeth BioPharma*

C13: Maximizing the Use of Production Downtime

Wyeth Biopharma has used creative ways of optimizing the training of staff during unique windows of opportunity of production downtime. Using a case study focused on the 2004 Andover facility shutdown period, this session will explain how Wyeth planned and implemented this training.



Rick Elmer, Sr. Training Manager,
AstraZeneca

C14: SME Trainer Certification: An Effective and Efficient Training Process Using Your Organization's Technical Resources as Certified OJT Instructors — An AstraZeneca Case Study

Learn how AstraZeneca challenged existing assumptions about how a training organization should be structured, and how it is now able to be positioned as a value-added service organization of three individuals supporting an organization of over 800 individuals.



Valerie Gamble, Training Project Manager,
Pfizer

C15: The Effectiveness of Blended Learning for the Employee

This session will present data on a study performed at a major pharmaceutical company in 2005. The study compared the benefits of blended learning to the employee as opposed to the business benefits. The session will use Lectora, an e-learning tool, as a medium to present the data.

■ 5:30 p.m. - 10:00 p.m.

Cruisin' in The City of Brotherly Love on the Spirit of Philadelphia

Step aboard the **Spirit of Philadelphia** at Penn's Landing for an evening of unparalleled cruising fun on the Delaware River. Enjoy dining, dancing, star-quality entertainers and breathtaking skyline views of Philadelphia on this luxurious harbor cruise

This opportunity to sail with your conference colleagues and enjoy spectacular views is included in your registration fee. Additional tickets may be purchased for \$90.00 per person (includes bus transportation).

Icon Key



Regulatory Updates – Better understand current regulatory requirements and leverage proven strategies to meet training and business needs



Technical Training – Learn new techniques, strategies and best practices to improve training performance



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Theory and Design – Examine new instructional design techniques, strategies and current theories for developing training programs

TUESDAY, MAY 9, 2006

■ 7:00 a.m. - 4:00 p.m.
Registration Open

■ 7:00 a.m. - 4:00 p.m.
Exhibit Area Open

■ 7:00 a.m. - 8:00 a.m.
Continental Breakfast in Exhibit Area

■ 7:00 a.m. - 4:00 p.m.
Demonstration/Display of Trainers' Choice Finalists' Materials (Ballots due by 4:30 pm)

■ 8:00 a.m. - 9:15 a.m.
P3: Plenary Session
FDA speaker invited

■ 9:15 a.m. - 10:30 a.m.
Concurrent Sessions



Michael Falkow, Managing Consultant,
Tunnell Consulting

C16: An Approach to Training Operations Personnel for FDA Pre-Approval Inspections

Learn more about one approach to train operations personnel to prepare for a Pre-Approval Inspection. Through this approach, personnel are ready and aware of FDA Pre-Approval Inspection practices, and personnel who do not usually interact with the FDA have a higher level of understanding.



Karen Murray, Training Specialist,
Wyeth BioPharma

C17: Development of an Investigator Certification Program: "How to Get a CLUE"

Learn how Wyeth uses a blended learning approach of system training, e-learning and classroom instruction to certify internal investigators.



Stacy Thompson, QA Education Coordinator,
Community Blood Center/Community Tissue Services

C18: Aligning Training to the Company's Business Strategy: Building a Strategic Training Plan

This session emphasizes the criticality of aligning the training plan to the company's strategic business plan, in order to position training as a solutions provider and an integral business partner in realizing business objectives.

Topics of discussion will include traditional areas of a training plan such as, conducting a needs assessment, identifying performance gaps and recommending learning solutions. They will also include the importance of understanding the business direction and aligning the training plan to business initiatives.



Michelle Nonatelli, Manager,
Glaxo Smith Kline, Biologicals

C19: Train the Trainer — Are Trainer Behaviors the Same as Presenter Behaviors?

In many pharmaceutical companies, managers, supervisors, QC staff and others are asked to perform training. But are they adequately prepared to do so?

This session will simulate different training scenarios and emphasize the importance of individual learning styles, the stages of learning and learning cycles. There will be a self test for trainers to evaluate themselves.



Lynn Pruitt-Timko, Training Professional,
Pfizer

C20: 5th-Shift: An Innovative Approach to Refresher Training

Pfizer has developed a 5th shift especially for training. Find out why this approach has been successful and what it is.

■ 10:30 a.m. - 11:00 a.m.
Refreshment Break & Demonstration/Display of Trainers' Choice Finalists in Exhibit Area

■ 11:00 a.m. - 12:15 p.m.
Concurrent Sessions



Diane Erhard, Director, Global Training and Continuous Improvement,
Wyeth Pharmaceuticals

Debra Gowett, Director, Global Training and Continuous Improvement,
Wyeth Pharmaceuticals

C21: Breakthrough Process Redesign — Improvements for Business and GMP

GMP trainers can expand their role to process redesign facilitators who help others to simplify compliance processes. This session will describe how compliance processes like validation, change control and even the training system can be improved using basic process improvement tools and change management principles.



David Gallup, PhD, Principal, *Training and Communications Group*

John Strachan, Senior Instructional Designer, *Training and Communications Group*

C22: Developing Internal Subject Matter Experts (SME) to Support Site Level Training Initiatives

SMEs are crucial to the success of a training program. However, many companies approach the selection of internal SMEs in an inconsistent and informal manner. Learn how to select SMEs and develop SMEs using a structured process.



Pamela Eddy, Training Associate, *Eli Lilly & Co.*

Roberta Talmage, Training Consultant, *Eli Lilly & Co.*

Rachelle Verkamp, Training Leader, *Eli Lilly & Co.*

C23: Creating the Annual Report for Training and Development

This session introduces an innovative evaluation process that combines the best of two evaluation methodologies — Brinkerhoff's Success Case Method and Phillip's ROI — to produce a complete "annual report" on training. The annual report provides stakeholders with the data they need to understand the full impact of training on an organization. A case study of an operator qualification program will be presented.

2006 PDA BIENNIAL TRAINING CONFERENCE AGENDA



Rick Rogers, GXP Trainer,
Independent Consultant

C24: 65 Reinforcement Techniques to Increase or Control Classroom Participation

Through interactive discussion, this session provides several simple techniques to improve and control participation in the adult classroom training. Dealing with the problem participant will be one topic of discussion.



Jason Fitz, Owner, *MaxCom Consulting*
Simon Rusmin, PhD, Owner, *New Spring Consulting*

C25: Design and Assessment of Effective “15 Minute” Training

Discover how a unique and innovative “small group-short sessions” approach can be effectively used. This session focuses on capturing the trainee’s attention, building relationships between the trainer and trainee, using real time assessment and connecting to the trainee’s actual work performance.

■ 12:15 p.m. - 1:30 p.m.
Networking Luncheon

■ 1:30 p.m. - 2:45 p.m.
Concurrent Sessions



Ivan Aviles, Training Associate,
Lilly del Caribe

C26: Business Partnering: Inspiring Relationships that Work

What business partners do trainers need to be aware of? What can they do to maintain these relationships? In this session you will be provided with a “tool box” that will help you to prepare, monitor and evaluate partnerships within your areas.



Megan McDermott, Training Specialist, *Wyeth*
Tracy Pratt, Operations Training Specialist, *Wyeth*
Maureen O’Neill, Operations Training Associate, *Wyeth*

C27: Systems Training: Bridging the Gap Between Automation and Compliance

As our industry incorporates more automation and computer systems into the workplace, trainers are challenged with the task of conducting systems training in a GMP environment. This presentation will focus on the following issues related to systems implementation:

- Trainers acting as project managers
- The differences between performing systems training and GMP classroom training
- Blended learning and other pedagogical approaches to systems training
- The challenge associated with performing in-suite automation training and classroom training



Dianne Debecker, QA Officer, *Genzyme Flanders*
Jon Voss, Sr. QA Director, *Genzyme Flanders*

C28: Effective GMP Training and Measuring its Effectiveness: A Case Study

Using a sample case study, this session will explore how one company implemented new training methods to improve overall training effectiveness and decrease the time spent recording training. Learn how more employees can be trained in a shorter period of time with increased e-learning retention.



Elaine Lehecka-Pratt, President,
Lehecka-Pratt Associates, Inc.

C29: 10 “Secrets” of Becoming a Better Trainer

Learn how to improve your training skills and share your ideas with other participants. This session will discuss a fast paced, “top ten” list of suggestions for improving training skills.



Roy Baxendale, Process Support Team Leader,
Delta Biotechnology Limited

C30: The UK & Ireland Chapter Training Best Practices Document

Delve into a discussion about the development and application of the PDA UK & Ireland Chapter Best Practices Training Document. This session will focus on the various sections of the document, the implementation of best practices and a summary of the requirements for applying a best practice training system.

■ 2:45 p.m. - 3:15 p.m.
Refreshment Break & Demonstration/Display of Trainers’ Choice Finalists in Exhibit Area

■ 3:15 p.m. - 4:30 p.m.
Concurrent Sessions



Antonio Moreira, Executive Vice President,
SPI USA, Inc.

C31: A Survey of Training Needs in the Biotechnology Industry

Training methods, topics and needs of the biotechnology industry will be outlined in this session. Training needs in the USA and Europe will also be discussed.



Joe Kudrewicz, Sr. Training Specialist,
AstraZeneca

C32: How to Train People Who do Your On-the-Job Training

Learn a hands-on approach to help people understand the key points of teaching employees how to deliver on-the-job training. Attendees will take part in a demonstration on teaching a simple task that can be applied to all types of jobs.



James Vesper, President,
LearningPlus

C33: In-, Out-, or Omni-Source: Advantages, Disadvantages and Tradeoffs

Using an outsourcing firm poses risks and costs to both pharmaceutical firms and suppliers. Determine how to manage and define these risks and the costs to create a mutual benefit for each party. Explore how to maximize these benefits.



Diana Watson, Sr. Training Associate, *Eli Lilly DC 500*
Kevin Thompson, Assistant Professor, *University of Minnesota*

C34: Developing an Effective and Functional Operator Qualification Program on a Shoestring Budget

All trainers are faced with doing more with less. In this session discover how Eli Lilly met the challenge of developing almost 200 courses in a short period of time using only in-house resources.

Icon Key



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Theory and Design – Examine new instructional design techniques, strategies and current theories for developing training programs



Maria Victoria Kahn, GMP Training Specialist III,
Amgen

C35: Using Systems Thinking in Designing Training Programs

This two-part, hands-on workshop will introduce you to the concept of systems thinking. Learn about the design training that addresses the continuous changes that affect business and job performance.

- 7:05 p.m.
New York Mets vs. Philadelphia Phillies (Optional Event) — \$50 (Includes ticket and transportation), Citizens Bank Park, Philadelphia, Pennsylvania

WEDNESDAY, MAY 10, 2005

- 7:00 a.m. - 4:15 p.m.
Registration Open
 - 7:00 a.m. - 8:00 a.m.
Continental Breakfast
 - 8:00 a.m. - 8:30 a.m.
2006 PDA Trainers' Choice Awards Presentation
 - 8:30 a.m. - 10:30 a.m.
Session P4: Keynote Presentation — Enhancing Training Effectiveness and Performance Results
Stephen G. Smith, Senior Vice President & Managing Executive,
Rummler-Brache Group, a Pritchett Company
- What You Will Learn**
- A simple and repeatable approach to measure the performance of your training processes
 - How to set metrics targets and goals for the training process to align performance with your corporate strategy for GMP compliance
 - How to determine the effectiveness of your training through the use of the Human Performance System
 - How to use feedback from performance results to continually improve your training processes
- 10:30 a.m. - 11:00 a.m.
Refreshment Break
 - 11:00 a.m. - 12:30 p.m.
Session P4: Keynote Presentation — Enhancing Training Effectiveness and Performance Results (continued)
Stephen G. Smith, Senior Vice President & Managing Executive,
Rummler-Brache Group, a Pritchett Company

- 12:30 p.m. - 1:30 p.m.
Lunch on your own
- 1:30 p.m. - 4:00 p.m.
Session P4: Keynote Presentation — Enhancing Training Effectiveness and Performance Results (continued)
Stephen G. Smith, Senior Vice President & Managing Executive,
Rummler-Brache Group, a Pritchett Company
- 4:00 p.m. - 4:15 p.m.
Closing Remarks
David Fant, 2008 Program Planning Committee Chair
- 4:15 p.m.
Conference Adjourns

SOCIAL/NETWORKING OPPORTUNITIES:

Meet and Greet Reception

Sunday, May 7, 5:00 p.m. – 6:00 p.m.

Pick up your registrations a day early and enjoy light refreshments and the opportunity to network with other conference attendees.

Cruisin' in The City of Brotherly Love

Monday, May 8, 5:30 p.m. – 10:00 p.m.

Step aboard the Spirit of Philadelphia at Penn's Landing for an evening of unparalleled cruising fun on the Delaware River. Enjoy dining, dancing and breath-taking skyline views of the Philadelphia harbor on this luxurious cruise.



One ticket for Cruisin' in the City of Brotherly Love is included in your registration fee. Additional tickets may be purchased for \$90.00 per person (including bus transportation).



New York Mets vs. Philadelphia Phillies (Optional)

Tuesday, May 8, 7:05 p.m.

Get ready for a National League East Division showdown when the New York Mets come to town to play the Philadelphia Phillies at Citizens Bank Park. Tickets for this event are available for \$50 each. Please note:

There is a limited amount of tickets, so attendees are advised to purchase them early. (The \$50 fee includes ticket and transportation).

Icon Key



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2006 PDA BIENNIAL TRAINING CONFERENCE INFORMATION

REGISTRATION INFORMATION

Registration Fees

	Before March 8	March 8 – May 5	After May 5
Member	\$1,050	\$1,250	\$1,350
Nonmember*	\$1,245	\$1,445	\$1,545
Government/Health Authority	\$ 430	\$ 510	\$ 550
Academic**	\$ 430	\$ 510	\$ 550
Student**	\$ 160	\$ 190	\$ 205

* Registration fee includes a one-year PDA membership. No additional payment is required.

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

Your Registration Includes:

- Full-day interactive workshop to analyze and measure your training processes and more
- Two fact-filled plenary sessions presented by regulatory experts
- High energy plenary session featuring the 2006 Biennial Training Conference Program Committee
- 35 concurrent workshops divided into five different learning tracks
- Sunday evening Meet and Greet Reception
- Continental breakfast each day
- Two coffee and refreshment breaks each day
- Two networking luncheons to explore the application of session information to your training environment
- Monday evening cruise on the Spirit of Philadelphia
- Conference notebook
- Informative vendor exhibits showcasing training products and services
- Demonstration/display of Trainers' Choice Award finalists' training materials

Three Ways to Register

- 1. FAX** +1 (301) 986-1093
- 2. CLICK** www.pda.org/training2006
- 3. MAIL** PDA Global Headquarters
3 Bethesda Metro Center
Suite 1500
Bethesda, MD 20814 USA

Registration Hours

(Badge pick-up and Onsite Registration)

Sunday: 3:00 p.m. - 5:00 p.m.

Monday: 7:00 a.m. - 4:30 p.m.

Tuesday: 7:00 a.m. - 4:00 p.m.

Wednesday: 7:00 a.m. - 4:15 p.m.

Dress/Attire

Business casual attire is recommended for the 2006 PDA Biennial Training Conference. Since the temperature in meeting rooms tends to be cool, 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 info@pda.org.

At the completion of this program, the participant will be able to:

- Improve the performance of your employees
- Present GXP training that engages your audience
- Inform your site of the latest regulatory requirements
- Network with other GXP trainers
- Apply the latest training trends and techniques

Continuing Education



PDA is approved by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmaceutical 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:

2006 PDA Biennial Training Conference

1.90 CEUs for 3.0 days/Full Conference
ACPE # 116-000-06-097-L04

Training Courses

- PDA #147:** cGXP – ACPE #116-000-06-147-L04 (0.6 CEUs)
- PDA # 245:** Making the Grade with the FDA – ACPE #116-000-06-245-L04 (0.6 CEUs)
- PDA #121:** Maximizing SOPs – ACPE #116-000-06-147-L04 (0.6 CEUs)
- PDA #126:** Regulation without Motivation – ACPE #116-000-06-147-L04 (0.6 CEUs)
- PDA #182:** Technical Training – ACPE #116-000-06-182-L04 (0.6 CEUs)
- PDA #169:** The Business of Training – ACPE #116-000-06-169-L04 (0.6 CEUs)
- PDA #225:** The Evolution of Training – ACPE #116-000-06-225-L04 (0.6 CEUs)
- PDA #196:** The Manager's Role in Training – ACPE #116-000-06-126-L04 (0.6 CEUs)

VENUE INFORMATION

Marriott Philadelphia Downtown

1201 Market Street
Philadelphia, PA 19107

Tel: + 1 (215) 625-2900

Fax: + 1 (215) 625-6000

Rate: Single / Double – \$209.00

plus 14% state and local taxes.



In the heart of the business district, this grand Philadelphia hotel commands a towering presence. Walk to the finest restaurants, shopping and entertainment the city has to offer, or take in the sites and sounds of some of our nation's best cultural and historic venues.

Reservations

To make your reservation, please call +1 (800) 228-9200 or visit www.pda.org/training2006.

A block of rooms has been reserved for PDA delegates. Be sure to reference the 2006 PDA Biennial Training Conference and reserve a room no later than Saturday April 15, 2006, to obtain the group rate as listed, or until PDA's room block has been filled (whichever comes first). **Housing at the Marriott Philadelphia Downtown will be in high demand, so we strongly recommend making your reservations early.**



2006 PDA BIENNIAL TRAINING COURSES

NEW CONCEPTS IN TRAINING!

The PDA Training and Research Institute (PDA TRI) is offering eight interactive courses designed to help you integrate training into your business strategy — a perfect complement to the 2006 Biennial Training Conference.

Learn about quality systems in training, training compliance issues, structure and function of training, return on investment (ROI), metrics and evaluation of training, and much more.

Not only will you gain up-to-date career-focused information, but you will be learning from leading experts in the pharmaceutical and biopharmaceutical industries ready to share their real-world experiences with you.

cGXP Training for the 21st Century May 11

**John Sicurella, Avecia
Biotechnology**

New Course!

Don't be stuck in the 1900s! It is now the 21st century — be sure your cGXP's reflect the age in which they are being used. This course will serve as an opportunity for you to assess the state of your company's training program relative to current industry standards. New/refined ideas and philosophies will be presented on how to optimize and mitigate, consequently making the cGMP training function more robust to ensure that it takes the giant step forward into the 21st century.

Making the Grade with the FDA May 12

**Barbara Van der Schalie,
MedImmune, Inc.**

New Course!

Is your company in line for an inspection by the FDA? Now is a great time to evaluate your training program. By course end, you will understand how to avoid the five most common FDA training findings and be able to remedy them if they exist in your program. You will also be able to conduct a risk-based assessment of training needs and evaluate those needs for prioritized implementation. Your training program will be ready to be examined by the FDA once you have implemented the tools provided in this course!

Maximizing SOPs – An Untapped Resource of Training Solutions

May 11

**Elaine Lehecka Pratt,
Lehecka Pratt Associates, Inc.**

SOPs are a great resource for training, so why not take advantage of them? This highly interactive course is designed to give you new skills, tools and ideas for using existing facility SOPs to develop training solutions to meet a variety of goals. You already have the resources at your disposal, so why not learn how to use them to your benefit? By providing you with the skills to unlock the valuable training potential of SOPs, the return on SOP investment is optimized.

Regulation without Motivation – Spark a Change without Shorting a Circuit May 12

Deborah Harrell Meehan, Bayer Corporation

Do you have an open mind and a sense of humor? Those are the only two prerequisites for this unique course! Explore tools and principles that will help you bring renewed motivation and energy to yourself, your training sessions and your work. Bring FUN to your workplace, and see the positive change not only in yourself, but in your employees as well. Not just for HR professionals and Training Managers, this course is intended for anyone who is interested in affecting change into their organization.

Technical Training as an Integral Part of an Aseptic Operation Quality System May 11

Eddie Balance, Eisai Inc.

New Course!

Are you involved in sterile and aseptic manufacturing? Do you want to set up an effective training program for manufacturing and support personnel? This interactive course is packed with case studies, 483s, sample training documents, group activities and more that will help you do just that! Work with the Code of Federal Regulations and the current Aseptic Processing Guidelines, develop a plan for getting new fill room personnel ready, identify poor practices in developing employee certification tests and develop a training SOP that is effective, flexible and clearly states the training expectations for your staff. The lessons learned in this course can be applied to build strong, effective and integrated training programs that include not only manufacturing personnel, but their support groups as well.

The Business of Training: Earnings and Learnings

May 12

Eric Rudolf, Millipore Corporation

New Course!

Have you done a training needs analysis and decided that training is the solution? Wondering how you will fund, develop and sustain such a solution? Have we got a course for you! This course will provide a case study in which the costs and benefits of developing and executing a training program are assessed and used to constrain or fund a program. You will leave with an understanding of the development, operating and maintenance costs of a program, as seen upon its inception and then measured years later.

The Evolution of Training: Keeping Pace with the Business and Regulatory Requirements

May 12

Gregg Sherman, Consultant

New Course!

Training is an essential part of business. Don't push it aside because you think your company is being properly trained — be positive! This course will provide a 'toolbox' of foundational skills and training know-how based on industry

examples and best practices. This course will center on many components of training and how they can help training professionals to anticipate and influence the role of training management as the organization grows and matures.

The Manager's Role in Training May 11

**David Gallup, EdD, Training
and Communications Group, Inc.**

New Course!

You've heard it before: Training is a valuable and necessary tool. This course will help you understand why training is so important. Discuss and explore the manager's role in creating and promoting an effective training program in his organization. Learn to develop a realistic budget and present your case to upper management. With the right tools, you can create a positive attitude toward training.

ACPE Credit

Each of these one-day courses is worth 0.6 CEUs.

Pricing Information

One-day Lecture Course

Member:	\$ 995
Nonmember:	\$1190
Government:	\$ 395
Health Authority:	\$ 395
Academic:	\$ 385
Student:	\$ 150

Early Bird Available!

If registration is received by March 11, 2006, receive \$100 off when you register for two courses.

2006 PDA BIENNIAL TRAINING TABLETOP EXHIBITION

Tabletop Exhibition May 8-9, 2006

PDA is seeking vendors who provide excellent services and support industry training to display their products and services in a Tabletop Exhibition. Refreshment breaks, lunches and receptions during the conference will provide great opportunities for networking with attendees. **Reserve your space today!**

Space is limited! If your company is interested in exhibiting or sponsoring activities for the conference, please contact Nahid Kiani at +1 (301) 656 5900 ext. 128 or Kiani@pda.org



2006 PDA Biennial Training Conference and Courses

Philadelphia, Pennsylvania • May 8-12, 2006

Registration is simple and fast...FAX, CLICK OR MAIL: FAX: +1 (301) 986-1093 (USA) | CLICK: www.pda.org/training2006
 MAIL: PDA Global Headquarters, 3 Bethesda Metro Center, Bethesda, MD 20814, USA

1 Contact Information

Mr. Ms. Dr.

Name (Last, First, MI)

Membership Number (for PDA member registrants only)

Job Title

Department

Company

Mailing Address

City

State/Province

ZIP+4/Postal Code

Country

E-mail

Business Phone

Fax

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

Please check appropriate fee (US\$).

Your registration includes: two lunches, networking cruise and reception in Exhibit Hall.

	Before March 8	March 8 - May 5	After May 5
Member	<input type="checkbox"/> \$1,050	<input type="checkbox"/> \$1,250	<input type="checkbox"/> \$1,350
Nonmember*	<input type="checkbox"/> \$1,245	<input type="checkbox"/> \$1,445	<input type="checkbox"/> \$1,545
Government/Health Authority	<input type="checkbox"/> \$ 430	<input type="checkbox"/> \$ 510	<input type="checkbox"/> \$ 550
Academic**	<input type="checkbox"/> \$ 430	<input type="checkbox"/> \$ 510	<input type="checkbox"/> \$ 550
Student**	<input type="checkbox"/> \$ 160	<input type="checkbox"/> \$ 190	<input type="checkbox"/> \$ 205

* Registration fee includes a one-year PDA membership. No additional payment is required. If you do not wish to become a member, please check here

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

Group Registration: Register 10 people from the same site and receive the eleventh registration FREE (by fax or mail only).

3 Additional Event Tickets

Additional ticket for spouse/partner for networking cruise.

\$90 x number of tickets = \$ _____
 (One ticket included with Full Conference Registration.)

Tickets for New York Mets vs. Philadelphia Phillies baseball game.

\$50 x number of tickets = \$ _____
 (price includes ticket and transportation)

Special Dietary Requirements (Please be specific)

4 TRI Course Registration

Please check appropriate fee (US\$).

If registration is received by March 11, 2006, receive \$100 off when you register for two courses (by fax or mail only).

	Member	Nonmember*	Government/ Health Authority	Academic**	Student**
PDA #147: cGXP Training for the 21st Century (May 11, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #121: Maximizing SOPs – An Untapped Resource of Training Solutions (May 11, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #182: Technical Training as an Integral Part of an Aseptic Operation Quality System (May 11, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #225: The Evolution of Training: Keeping Pace with the Business and Regulatory Requirements (May 12, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #245: Making the Grade with the FDA (May 12, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #126: Regulation without Motivation: Spark a Change without Shorting your Circuit (May 12, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #169: The Business of Training: Earnings and Learnings (May 12, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150
PDA #196: The Manager's Role in Training (May 11, 2006)	<input type="checkbox"/> \$995	<input type="checkbox"/> \$1,190	<input type="checkbox"/> \$395	<input type="checkbox"/> \$395	<input type="checkbox"/> \$150

* Registration fee includes a one-year PDA membership. No additional payment is required. If you do not wish to become a member, please check here

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

5 Payment Options

Please check one. All cards are charged in US\$.

Group Registration: Register 10 people from the same site and receive the eleventh registration FREE (by fax or mail only).

PDA Federal Tax I.D. #52-1906152

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

Please bill my: American Express MasterCard VISA Diners Club Total amount: _____

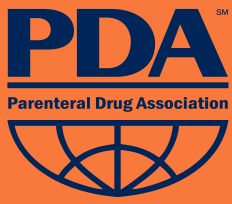
Account Number _____ Credit Card Verification # _____ Exp. Date _____

Name (exactly as it appears on card) _____ Signature _____

FOR OTHER PAYMENT OPTIONS PLEASE GO TO WWW.PDA.ORG/TRAINING2006

Deadline: Paid registrations must be received one week prior to the event. **Confirmation:** Written 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. **Substitutions:** If a registrant is unable to attend, substitutions are welcome and can be made at any time, even on-site up to the time of the course. If you are pre-registering as a substitute attendee, indicate this on the registration form. Refunds: All refunds must be in writing. Refunds for Conference/Event: Registrants whose written requests are received on or before April 10, 2006 will get a full refund minus a \$55 handling fee. If a request for refund is received after April 10, 2006 or on/before April 24, 2006, one-half of the registration fee will be refunded. After that time, no refunds will be made. **Refund for Courses:** Registrants whose written requests for refunds are received at least three weeks prior to the date of the course will receive a full refund less a \$200 processing fee. Onsite registrants are not guaranteed to receive a conference binder until all advanced registered attendees receive one. **Event Cancellation:** PDA reserves the right to modify the material or instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified as soon as possible and will receive a full refund of fees paid. PDA will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. For more details, call PDA at +1 (301) 656-5900.

PDA USE ONLY Date: _____ Check: _____ Amount: _____ Account: _____



Connecting People, Science and RegulationSM

2006 PDA BIENNIAL TRAINING CONFERENCE

PHILADELPHIA, PENNSYLVANIA • MAY 8 – 12



TRAINING ... A WINNING STRATEGY

This year's PDA Biennial Training Conference is a must-attend event!

- 35 concurrent sessions with five job-focused tracks
- Interactive workshop by keynote speaker Steven G. Smith
- FDA speakers confirmed
- Trainers' Choice Awards
- Eight PDA TRI courses designed to help you integrate training into your business strategy
- New technology vendor exhibition



PDA
3 Bethesda Metro Center, Suite 1500
Bethesda, MD 20814
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296

**Register by March 7th (for conference) and
March 11th (for courses) for Early Bird Discounts**

www.pda.org/training2006