



2012 PDA ANNUAL MEETING

*Manufacturing Innovation: Achieving Excellence in Sterile
and Emerging Biopharmaceutical Technology*

April 16-18, 2012

JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA



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"This conference was
very well organized and
the content was very
well suited for everybody
involved with parenteral
manufacturing."

DK, Millipore



www.pda.org/annual2012

EXHIBITION: April 16-17 | **CAREER FAIR:** APRIL 16-17
POST-CONFERENCE WORKSHOP: April 18-19 | **COURSES:** April 19-20

This preliminary agenda is current as of November 22, 2011.



“The 2011 PDA Annual Meeting was a tremendous event for people in all facets of the industry. It was well worth the trip from Australia to hear, see and participate in discussion relating to key topics impacting on our industry.”

Ano Xidias,
PharmOut Pty Ltd.

Program Planning Committee

Co-Chair:

Vince Anicetti

Keck Graduate Institute of Applied Life Sciences

Co-Chair:

Marsha Hardiman

Dendreon Corporation

Harold Baseman

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Kurt Brorson, PhD

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MedImmune

Miguel Montalvo

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Abbott Medical Optics (AMO)

Mike Sadowski

Baxter Healthcare Corporation

Christopher Smalley, PhD

Merck and Company

Patricia Stancati

Sartorius Group North America

A Message from the Program Chair Co-Chairs

Dear Colleagues and Friends,

The 2012 PDA Annual Meeting will highlight a number of the more exciting and daunting challenges before our industry today. Chief among these challenges are “right the first time” sterile dosage form production in the global environment, developing flexible and economic large scale cell culture production systems and control strategies for emerging cellular therapies. These areas of biopharmaceutical manufacturing are at the forefront of the reliability and economic improvements needed to help the increasingly complex medicines reach a greater numbers of patients. The expertise of PDA’s global membership and their commitment to develop scientifically sound and practical solutions will make the 2012 PDA Annual Meeting an important event for anyone involved in the areas of sterile or biopharmaceutical production.

Two distinguished leaders in the advancement of cancer therapy will address the opening plenary session. **David Shanahan**, President of the *Mary Crowley Research Center* and CEO and Founder of *Gradalis Inc.*, will provide an entrepreneurial vision for the transformation of cancer treatment through personalized medicine. Joining him will be **Dr. Ted Love**, a pioneering physician/scientist in the development of cancer and cardiovascular biotechnology derived therapies. Dr. Love will use his perspectives as Executive Vice President, R&D and Technical Operations at *Onyx Pharmaceuticals* and a board member of the *California Institute for Regenerative Medicine* to present the exciting scientific opportunities ahead for innovative cellular therapies as well as the technical and regulatory challenges.

Two important areas of biotechnology highlighted in the 2012 meeting are manufacturing innovation and emerging technologies. Heading the biotechnology manufacturing innovation track will be advances in large-scale cell culture techniques. Innovations in high titer production systems and best practices in contract manufacturing are two of the many important topics that will be covered. Cellular therapies and combination products will lead the themes highlighted in the emerging biotechnology arena. In addition, lessons learned in the manufacture and control of recently approved cell based cancer therapies will be presented along with current regulatory viewpoints. Control strategies for biopharmaceuticals will comprise the third focus track for the annual meeting. Track highlights will include risk-based approaches to lifecycle management and cost efficient solutions in the quality control arena.

Lastly, personal career development strategies will be highlighted in a special breakfast panel discussion at the meeting. Three widely respected experts, **Cheri Spolin** of *Genentech*, **Roy Blitzer** of *RJB Consulting* and **Dave Fortier** of *ZRG Partners* will share their insights on career advancement and changing organizational roles; using your network and successful leadership traits of technical executives.

New in 2012! The Program Planning Committee encourages students to submit an abstract for poster presentation. Abstracts must be noncommercial, describe developments, strategies or work and significantly contribute to the body of knowledge relating to pharmaceutical manufacturing, process knowledge, quality management and technology. Abstracts related to sterile product manufacture, cellular and gene therapy, or production of biopharmaceuticals are preferred but those addressing other technologies are welcome. All abstracts will be reviewed by the Program Planning Committee for consideration. To review submission guidelines and submit an abstract please visit www.pda.org/annual2012.

Immediately following the Annual Meeting on April 19th and 20th, PDA’s Training and Research Institute (PDA TRI) will be holding eight courses designed to complement what you have learned during the meeting. Plan to stay in Phoenix for another day or two and take advantage of one of these learning opportunities.

Don’t miss the 2012 PDA Annual Meeting. It will keep you abreast of the latest innovations in biopharmaceutical manufacturing and emerging cellular technologies to advance your firm and career.

Best Regards,



Vince Anicetti
Adjunct Professor, *Keck Graduate Institute of Applied Life Sciences*
Co-Chair, 2012 PDA Annual Meeting
Program Planning Committee



Marsha Hardiman
Senior Manager Corporate Quality Control, *Dendreon Corporation*
Co-Chair, 2012 PDA Annual Meeting
Program Planning Committee

Sunday, April 15-Monday, April 16, 2012 Agenda

Sunday, April 15, 2012

7:30 a.m. – 12:00 p.m.

6th Annual PDA Golf Tournament at the Wildfire Golf Club

8:00 a.m. – 10:00 a.m.

PDA's 6th Annual Walk/Run
(Benefiting the Phoenix Children's Hospital)
Sponsored by Sartorius Stedim Biotech



11:00 a.m. – 4:30 p.m.

Regulatory Affairs & Quality Advisory Board

2:00 p.m. – 6:00 p.m.

Registration Open

3:00 p.m. – 6:00 p.m.

Speaker Ready Room Open

3:00 p.m. – 6:00 p.m.

Meet and Greet Reception

3:00 p.m. – 4:00 p.m.

2012 Program Planning Committee Meeting (Invitation Only)

6:30 p.m. – 9:30 p.m.

PDA Awards Dinner (Invitation Only)

Monday, April 16, 2012

7:00 a.m. – 5:30 p.m.

Registration Open

7:00 a.m. – 8:00 a.m.

Continental Breakfast

7:00 a.m. – 8:00 a.m.

New Member Breakfast (Invitation Only)

Welcome new PDA members! Join us for breakfast to learn more about PDA and to meet other new members, board members and staff.

7:00 a.m. – 5:00 p.m.

Speaker Ready Room Open

8:30 a.m. – 8:45 a.m.

Welcome, Opening Remarks and PDA Award Announcements

Anders Vinther, PhD, Vice President, Quality Biologics,
Genentech, Inc., and Chair, *PDA Board of Directors*

Richard M. Johnson, President, *PDA*

Vince Anicetti, Adjunct Professor, *Keck Graduate Institute of Applied Life Sciences* & Marsha Hardiman, Senior Manager
Corporate Quality Control, *Dendreon*

8:45 a.m. – 10:30 a.m.

Opening Plenary Session

Moderator: Vince Anicetti, Adjunct Professor, *Keck Graduate Institute of Applied Life Sciences*

Advances in gene and cellular therapy have allowed new treatment approaches and hope for patients with a wide range of serious and life threatening disorders. In this session David Shanahan will present a vision for the future of cancer treatment and the efforts underway at the Mary Crowley Institute to realize that vision. David will share the story of the institute and the belief that a paradigm shift is occurring in cancer care by which personalized medicine will ultimately transform the way patients are treated. With an ultimate goal to cure cancer, the ongoing objective at Mary Crowley is to administer novel agents in innovative ways to transform cancer into a manageable disease. Today Mary Crowley Institute is involved in over 200 FDA approved trials. Stem cell therapy provides new promise for a diverse range of disorders including cancer, spinal cord injuries, and a broad range of human degenerative diseases. Realizing this promise will require fundamental understanding of stem cell biology. The mission of California Institute for Regenerative Medicine (CIRM) is to support and advance stem cell research and regenerative medicine under the highest ethical and medical standards for the discovery and development of cures, therapies, diagnostics and research technologies to relieve human suffering from chronic disease and injury. As a board member of CIRM, Dr. Ted Love will share the promising safety and efficacy results of stem cell therapies to date, but also the challenges ahead in making these therapies widely available. Challenges relating to investigational product development, chemistry, manufacturing and controls (CMC) strategies, product characterization and comparability and evolving regulatory requirements are a few of the challenges that Dr. Love will describe from his view at CIRM.

8:45 a.m. – 9:30 a.m.

Future Benefits for Patients: From Discovery to Commercial Products, Cellular and Gene Therapies

David Shanahan, President, *Mary Crowley Research Center* and President, CEO and Founder, *Gradalis*

9:30 a.m. – 10:00 a.m.

The Future of Personalized Medicine - Challenges Ahead

Ted Love, MD, Executive Vice President, R&D and Technical Operations, *Onyx Pharmaceuticals*

10:00 a.m. – 10:30 a.m.

Q&A

10:15 a.m. – 7:00 p.m.

Exhibit Hall Open

10:30 a.m. – 11:15 a.m.

Refreshment Break and Poster Presentations in Exhibit Hall

Monday, April 16, 2012 Agenda (continued)

11:15 a.m. – 12:45 p.m.

Concurrent Sessions

Innovation and Productivity in Large Scale Manufacturing	Personalized Medicine/Cellular Therapeutics	Control Strategies for Biopharmaceuticals
<p>A – Microbial Control in the Manufacturing Environment: Advanced Aseptic Technology Moderator: Rick Lu, Director, Manufacturing, <i>MedImmune</i></p>	<p>B – Challenges in Manufacturing and QA/QC Part I Moderator: Marsha Hardiman, Senior Manager Corporate Quality Control, <i>Dendreon</i></p>	<p>C – Current Practices and Opportunities in Biopharmaceuticals Moderator: Philippe Gomez, Key Accounts Manager, <i>Sartorius Stedim Biotech</i></p>
<p>Aseptic processes represent a challenge of their own as controlling microbial contaminants is a matter of probability and risks associated to the process and the environment surrounding it. As we move into the 21st century with increased scrutiny and diligence; managing, controlling and monitoring an aseptic process becomes very costly and potentially inefficient. Alternative methods may also be used to monitor and control the process from potential microbial contaminants. This session will discuss alternative methods for assuring a sterility assurance level suitable for your process and product. The session will discuss innovative technology as well as the implementation strategy using a risk based approach focused on product quality while increasing product output.</p>	<p>Personalized medicine represents an exciting future direction for the pharmaceutical business. It represents patient specific treatments tailored to each patient’s cells and tissues. Current FDA approved personalized medicines are on the market for cancer. Other personalized medicines are in development with aspirations of commercial production in the near future. Along with the manufacturing of these types of products comes interesting and new challenges for both operations and quality departments. The rules for traditional biopharmaceutical manufacturing do not always apply. Compendial and regulatory requirements for aseptic manufacturing and quality testing of sterile products, which were created for traditional pharmaceutical manufacturing, need to be followed, yet often need to be implemented in a different way. In personalized medicine, lot release may need to take place in hours after production versus days, weeks or months after production. Investigations need to be opened, executed and completed in hours, not days to allow for product disposition. This session will expose attendees to real life challenges related to quality control testing, quality assurance and manufacturing of personalized medicine products.</p>	<p>The biopharmaceutical industry remains strong and growing. Pharmaceutical companies continue their efforts to reduce costs and improve internal efficiency, while still continuing to increase their involvement in biopharmaceutical development and manufacture in an attempt to increase the percentage of biopharmaceuticals in their pipeline. This session addresses the current practices, and innovations in the manufacturing processes of biopharmaceuticals and upstream and downstream opportunities for new as well as for existing established processes. Increasing yield, implementing (or incorporating) new technologies and innovations, scaling up, while maintaining product quality and attributes...are some of the points that will be discussed during this first session of the Biopharmaceutical track.</p>
<p>11:15 a.m. – 11:45 a.m. Ophthalmic Industry Case Study Barry Ressler, PhD, Chairman and CEO, Triton Thalassic Technologies, Inc.</p> <p>11:45 a.m. – 12:15 p.m. Challenges of Implementation, Validation and Application in BDS Manufacturing and Fill/Finish Operations Ren-Yo Forng, PhD, Site Microbiologist, MedImmune</p> <p>12:15 p.m. – 12:45 p.m. Q&A</p>	<p>11:15 a.m. – 11:45 a.m. Challenges in QA/QC Greg Whitehead, Director, Corporate Quality Assurance, Dendreon</p> <p>11:45 a.m. – 12:15 p.m. Challenges in Manufacturing John E. Butler, PhD, Global Project Leader, Bayer Innovation</p> <p>12:15 p.m. – 12:45 p.m. Q&A</p>	<p>11:15 a.m. – 11:45 a.m. Updating a Legacy Process: Plasma Fractionation Carol L. Anderson, Senior Process Engineer, Grifols, Inc.</p> <p>11:45 a.m. – 12:15 p.m. Poxvirus Aseptic Process Stephen Brown, PhD, Chief Technology Officer, Vivalis</p> <p>12:15 p.m. – 12:45 p.m. Q&A</p>

12:45 p.m. – 2:15 p.m.

Networking Luncheon in Exhibit Hall



Monday, April 16, 2012 Agenda (continued)

12:45 p.m. – 2:15 p.m.

Chapter Council Meeting

2:15 p.m. – 3:45 p.m.

Concurrent Sessions

Innovation and Productivity in Large Scale Manufacturing	Personalized Medicine/Cellular Therapeutics	Control Strategies for Biopharmaceuticals
<p>D – Microbial Control in the Manufacturing Environment: Advanced Sterilization Techniques Moderator: Miguel Nogueras, Global Manager of QA, <i>Abbott Medical Optics</i></p>	<p>E – Challenges in Manufacturing and QA/QC Part II Moderator: Harold S. Baseman, Chief Operations Officer, <i>ValSource, LLC</i></p>	<p>F – Contamination Control Moderator: Kurt Brorson, PhD, Biologist, <i>CDER, FDA</i></p>
<p>Terminal sterilization has long been held as the preferred method of sterility assurance for drug products since the drug products are sterilized within their final container closure systems. However, its application has been limited to those products that can withstand the harsh conditions of the sterilization process. With a growing market of biologic products, combination products as well as an existing market of sensitive small molecule products, the industry has pursued advances in terminal sterilization to address these needs. This session will discuss recent developments in terminal sterilization technologies and their application hurdles that provide enhanced sterility assurance for those products have historically been unable to withstand existing sterilization methods.</p>	<p>Personalized medicine represents an exciting future direction for the pharmaceutical business. It represents patient specific treatments tailored to each patient’s cells and tissues. Current FDA approved personalized medicines are on the market for cancer. Other personalized medicines are in development with aspirations of commercial production in the near future. Along with the manufacturing of these types of products comes interesting and new challenges for both operations and quality departments. The rules for traditional biopharmaceutical manufacturing do not always apply. Compendial and regulatory requirements for aseptic manufacturing and quality testing of sterile products, which were created for traditional pharmaceutical manufacturing, need to be followed, yet often need to be implemented in a different way. In personalized medicine, lot release may need to take place in hours after production versus days, weeks or months after production. Investigations need to be opened, executed and completed in hours, not days to allow for product disposition. This session will expose attendees to real life challenges related to quality control testing, quality assurance and manufacturing of personalized medicine products.</p>	<p>Biopharmaceutical products are challenged by a unique spectrum of potential contaminants: process/product related impurities, adventitious agents, and mycoplasma. Control strategies for these have been described in ICH guidance (ICH Q5A, ICH Q6B) as well as recent PDA technical reports (TR 41, 47 and 50). This session will address this unique spectrum of contaminants and strategies firms can implement to address them.</p>
<p>2:15 p.m. – 2:45 p.m. Low Dose Gamma Terminal Sterilization of Biologics Niki Fidopiastis, Director, <i>SteriPro Consulting, Sterigenics</i></p> <p>2:45 p.m. – 3:15 p.m. NO₂ Sterilization in place of ETO for Combination Products David Opie, PhD, Vice President, Research and Development, <i>Noxilier, Inc.</i></p> <p>3:15 p.m. – 3:45 p.m. Q&A</p>	<p>2:15 p.m. – 2:45 p.m. Industry Perspective: Challenges in Manufacturing of Personalized Medicine Stephen Brown, PhD, Chief Technology Officer, <i>Vivalis</i></p> <p>2:45 p.m. – 3:15 p.m. FDA Representative (Invited)</p> <p>3:15 p.m. – 3:45 p.m. Q&A</p>	<p>2:15 p.m. – 2:45 p.m. Update on Technical Report 50 Barbara Potts, PhD, Principal, <i>Potts and Nelson</i></p> <p>2:45 p.m. – 3:15 p.m. The MIT Consortium on Adventitious Agent Contamination Michael Wiebe, PhD, President, <i>Quantum Consulting, LLC</i></p> <p>3:15 p.m. – 3:45 p.m. Q&A</p>

Monday, April 16, 2012 Agenda (continued)

3:45 p.m. – 4:30 p.m.

Refreshment Break and Poster Presentations in Exhibit Hall

4:30 p.m. – 6:00 p.m.

Concurrent Interest Groups

<p>IG1 – Microbiology/ Environmental Monitoring</p>	<p>Leader: Jeanne E. Moldenhauer, Vice President, <i>Excellent Pharma Consulting, Inc.</i></p>	<p>The Microbiology/Environmental Monitoring Interest Group will discuss the issues of fungal contamination in the pharmaceutical process. Jim Polarine of Steris will discuss several of the recent issues with fungal contamination and ways that this can be addressed. Additionally, Brian Hubka and Vladimir Podlipsky of Pegasus Pharmaceuticals will speak on emerging technology to prevent fungal contamination. Following these two presentations, there will be time for discussion among the attendees and speakers.</p> <p>Brian Hubka, Pegasus Pharmaceutical Vladimir Podlipsky, Pegasus Pharmaceutical</p>
<p>IG2 – Process Validation</p>	<p>Leaders: Scott Bozzone, PhD, Senior Manager, Global QO Validation, <i>Pfizer, Inc.</i> Harold S. Baseman, Chief Operations Officer, <i>ValSource, LLC</i></p>	<p>The Process Validation Interest Group will present the new PDA PCMO Technical Report on <i>Process Validation and Verification</i>. The leaders will discuss the EMA intentions on Process Validation and follow-up on two (2) Concept Papers that were issued in early 2011. The session will also feature feedback on the U.S. FDA Guidance on Process Validation and how it is being received one year after the release.</p>
<p>IG3 – Quality Systems</p>	<p>Leader: Anders Vinther, PhD, Vice President, Quality Biologics, <i>Genentech, Inc.</i></p>	<p>The PDA Quality Systems Interest Group is a network of QA/QC professionals. Past topics have dealt with diverse subjects ranging from Systems Based Inspections, to QA /QC Organizations, to Risk Analysis. The Quality Systems Interest Group also sponsors a Quality Systems Forum on the PDA Web site for daily networking opportunities. Members participate in Task Forces on Compliance and Quality related topics. FDA Representative (Invited).</p>
<p>IG4 – Prefilled Syringe</p>	<p>Leaders: Thomas Schoenknecht, PhD, Director, Global Key Accounts Management, <i>Schott</i></p>	<p>The Pre-filled Syringe Interest Group will focus in an open discussion forum style on actual topics related to pre-fillable injection system components for drug delivery such as cartridges or syringes and combinations thereof with injection and safety devices. Latest trends and regulatory requirements for primary packaging material, track and trace systems, auto injector requirements on primary containers as well as alternative sterilization methods for material incorporation into isolator systems will be presented and discussed in an open forum. A special focus will be given on recent recalls and their impact on primary packaging material requirements.</p>

Monday, April 16-Tuesday, April 17, 2012 Agenda (continued)

IG5 – Visual Inspection of Parenterals

Leader:
John G. Shabushnig, PhD,
Senior Manager, Quality
Systems and Technical
Services, *Pfizer*

The Visual Inspection of Parenterals Interest Group provides a forum to discuss topics related to the visual inspection of injectable products. Past topics have included selection and qualification of human inspectors, validation of automated inspection systems, recent regulatory activity and country specific inspection requirements. This group has also initiated activities to survey industry inspection practices, organize special meetings on visual inspection and to provide scientific guidance on compendial requirements for the inspection of injectable products.

IG6 – Lyophilization and Vaccines

Leaders:
Edward H. Trappler,
President, *Lyophilization
Technology, Inc.*
Frank S. Kohn, PhD,
Principal Consultant,
FSK Associates

Lyophilization: As a constantly developing field there are always new perspectives in the science, technology and compliance realms. This interest group provides an open forum for discussions on current topics. Topics are identified at the onset of the meeting for open discussions among participants. This provides a unique opportunity to learn from a variety of experiences and perspectives and provides an excellent benchmark for current industry practices.

Vaccines: The session agenda includes a review of the critical issues facing the vaccine industry. This includes recent FDA issues.

IG7 – Supply Chain Management

Leader:
Lucy Cabral, Director,
Supplier and
Distribution,
Genentech, Inc.

The Supply Chain Management Interest Group offers its members the opportunity to influence the suppliers of the pharmaceutical and biotech industry to develop requirements that meet the needs of the industry in the areas of material quality, continuous improvement efforts, supply chain security, and supplier/customer business partnerships. The Interest Group will use existing information gathered from PDA members, suppliers, other industry groups, and drug manufacturers to document and develop best practices approach for suppliers to meet customer requirements globally.

5:30 p.m. – 7:00 p.m.
Networking Reception in Exhibit Hall

7:00 p.m. – 8:00 p.m.
Chairs Reception (Invitation Only)

Tuesday, April 17, 2012

7:30 a.m. – 5:45 p.m.
Registration Open

7:30 a.m. – 5:45 p.m.
Speaker Ready Room Open

7:30 a.m. – 8:30 a.m.
Continental Breakfast



Tuesday, April 17, 2012 Agenda (continued)

NEW
THIS
YEAR!

7:30 a.m. – 8:30 a.m.

Breakfast Session: Career Development Strategies

Moderator: Vince Anicetti, Adjunct Professor, *Keck Graduate Institute of Applied Life Sciences*

Strategies and tips for advancing your career will be discussed by three respected and highly experienced experts in biopharmaceutical recruiting and leadership development. The session will use a panel discussion format addressing audience questions. Cheri Spolin is highly accomplished senior HR executive with Genentech who has held senior HR positions in a number of high tech organizations. She will present the perspective of a corporate senior HR manager discussing successful strategies and techniques for internal career transitions and successful navigation of corporate cultures. As a widely respected executive coach, Roy Blitzer has served as a career strategy advisor to many senior executives in the biopharmaceutical industry over the past three decades. He will share his insights on the developing many of the important leadership and networking skills needed to advance from the technical arena into senior management as well as highlighting fatal career derailers to avoid. Dave Fortier is a highly regarded executive recruiter of senior quality, manufacturing and development positions for global biopharma. Dave will share his observations and advice on current trends in biopharmaceutical recruiting, as well as the attributes and experiences most sought after in today's executive job market. Don't miss this opportunity to understand today's demanding job market from some of the industry experts in career and leadership development.

Topics in this session will include:

- Career advancement and changing roles in your organization
- Developing leadership skills
- Career strategies
- Using your network

7:30 a.m. – 7:50 a.m.

Cheri Spolin, Human Resources, *Genentech*

7:50 a.m. – 8:10 a.m.

Roy Blitzer, Executive Coach, *RJB Consulting*

8:10 a.m. – 8:30 a.m.

Dave Fortier, Managing Director/Executive Recruiter, *ZRG Partners*

8:00 a.m. – 9:30 a.m.

Exhibit Space Draw

8:30 a.m. – 10:00 a.m.

Plenary Session 2

Moderator: Marsha Hardiman, Senior Manager Corporate Quality Control, *Dendreon*

What does the future of the biopharmaceutical industry look like? This session will address new trends in the industry. It's a time of unprecedented opportunity with new medical needs of patients and emerging technologies such as personalized medicine and cell therapies to help meet those needs. In this session, we will look into the future and discuss future biologics and future manufacturing processes and the financial impact on the pharmaceutical industry.

8:30 a.m. – 9:00 a.m.

The Future of the Biopharmaceutical Industry

David Urdal, Chief Scientific Officer, *Dendreon* (Invited)

9:00 a.m. – 9:30 a.m.

Financial Analyst Perspective on the Pharmaceutical Industry

Barbara A. Ryan, Managing Director, Research Analyst, *Deutsche Bank Securities, Inc.* (Invited)

9:30 a.m. – 10:00 a.m.

Q&A

9:45 a.m. – 4:30 p.m.

Exhibit Hall Open

10:00 a.m. – 10:45 a.m.

Refreshment Break, Poster Presentations and Passport Raffle Drawing in Exhibit Hall



Tuesday, April 17, 2012 Agenda (continued)

10:45 a.m. – 12:15 p.m.

Concurrent Sessions

Innovation and Productivity in Large Scale Manufacturing	Large Scale Production of Biopharmaceuticals	Control Strategies for Biopharmaceuticals
<p>G – Bioburden and Biofilm Management Strategies Moderator: Mike Sadowski, Director Sterile Manufacture Support, <i>Baxter Healthcare</i></p> <p>Biofilms have recently garnered much attention across our industry and have been frequently highlighted in recalls, warning letters and regulatory inspection citations. A biofilm is a complex aggregate of living microorganisms attached to a substrate in a self-derived structure that is capable of providing advanced protection and proliferation benefits to the microbial residents of this community. Wet pharmaceutical and biopharmaceutical production processes face the threat of biofilm colonization and associated risks to product quality. In this session, recognized experts on biofilms will provide up-to-date background information and share their expertise through a series of case studies to illustrate proper equipment design, detection, control and eradication measures intended to minimize biofilm risks.</p>	<p>H – Manufacturing Innovation Part I Moderator: Christopher Smalley, PhD, Associate Director, BioSterile Validation, <i>Merck</i></p> <p>This session is part 1 of a two part series on manufacturing innovation. Manufacturing processes need to constantly improve to remain cost effective in a competitive marketplace, and to remain compliant in the face of increasing regulatory expectations. Large scale manufacturing innovation includes an increased use of Single-Use Systems, innovative bioprocessing technologies and outsourcing to contract manufacturing organizations (CMOs). In this session, we will examine two case studies which describe the implementation of Single-Use Systems technology. Examples will be given of careful evaluation of new technologies and an implementation process employed to maximize innovative potential while minimizing disruption to existing operations and relevant elements of the Quality System. Session K will address innovative bioprocesses and the use of CMOs.</p>	<p>I – Quality Control/Testing Moderator: Jose Goin, PhD, Associate Director, Quality Control Network Group, <i>Genentech, Inc.</i></p> <p>The control of analytical methods is a critical part of QC testing operations. This session will focus on the strategies for understanding and managing the analytical method lifecycle, including maintenance, validation and transfer of analytical technologies in the Quality Control laboratory.</p>
<p>10:45 a.m. – 11:15 a.m. Genesis and Detection of Biofilm Marc Mittelman, PhD, Senior Managing Scientist, <i>Exponent</i></p> <p>11:15 a.m. – 11:45 a.m. Design and Control Strategies to Minimize Biofilm Risk Mark Pasmore, Senior Principle Engineer, <i>Baxter Healthcare Corporation</i></p> <p>11:45 a.m. – 12:15 p.m. Q&A</p>	<p>10:45 a.m. – 11:15 a.m. Case Study: Implementation of Disposable Systems for Buffer Delivery Claire Frazier, Senior Associate Process Development Engineer, <i>Grifols, Inc.</i></p> <p>11:15 a.m. – 11:45 a.m. Using Single Use Technology at Large Scale Chuck Hart, Director of Cell Culture, <i>Shire</i></p> <p>11:45 a.m. – 12:15 p.m. Q&A</p>	<p>10:45 a.m. – 11:15 a.m. The Late-Stage Analytical Method Lifecycle: Risk-based Validation and Maintenance Strategies Stephan Krause, PhD, Principal Scientist/ Associate Director, <i>Medimmune</i></p> <p>11:15 a.m. – 11:45 a.m. Approaches to Ensuring Analytical Method Robustness During Vaccine Product Life Cycle Garry Tackle, Manufacturing Division, <i>Merck</i></p> <p>11:45 a.m. – 12:15 p.m. Q&A</p>

11:00 a.m. – 12:00 p.m.

Exhibit Committee Meeting

12:15 p.m. – 1:45 p.m.

Networking Luncheon in Exhibit Hall

Tuesday, April 17, 2012 Agenda (continued)

12:15 p.m. – 1:45 p.m.

Biotechnology Advisory Board Meeting (Invitation Only)

12:15 p.m. – 1:45 p.m.

Science Advisory Board

1:45 p.m. – 3:15 p.m.

Concurrent Sessions

Innovation and Productivity in Large Scale Manufacturing	Large Scale Production of Biopharmaceuticals	Control Strategies for Biopharmaceuticals
<p>J – Combination Products Challenges and Considerations Moderator: Michele Creech, Quality Operations Manager, <i>Grifols, Inc.</i></p> <p>With the emergence of new technologies for creating combination products, challenges and opportunities for innovation arise. These “drug delivery systems of the future” are created by combining drugs and devices, drugs and biologics or devices and biologics to create new products. The diversity of the combinations that can be created means that industry and regulators cannot use a “one size fits all” approach when considering these unique entities, especially in the areas of depyrogenation and sterilization. Some of the factors to consider include single-entity vs. co-packaged vs. separately packaged products and whether to address the component parts before or after they are combined. These topics and more will be discussed during this session.</p>	<p>K – Manufacturing Innovation Part II Moderator: Ursula Busse, PhD, Head of Project Office, Global Biopharmaceutical Operations, <i>Novartis</i></p> <p>In the second session on manufacturing innovation, we will address improved upstream processing and contract manufacturing as two additional strategies to reduce cost of goods, while increasing efficiency and flexibility. In the first presentation on high yield expression systems you will learn how very high cell densities were achieved to increase product titer, and how downstream processing was modified to purify high titer harvests. The technologies make use of Single-Use Systems and are integrated in the design of DSM’s Biologics Plant of the Future, built in Brisbane, Australia. The second presentation on contract manufacturing will analyze and discuss lessons learned from a broad range of biopharmaceutical projects developed successfully at a CMO in collaboration with its contract givers. The focus will be on the key elements of the process leading to successful commercial supply collaboration.</p>	<p>L – Process Control/Validation Moderator: Jeffrey Hartman, Validation Manager, <i>Merck</i></p> <p>This session will begin with a case study highlighting the validation of a lyophilization cycle for a recombinant protein in a unique drug product device, a dual-chamber cartridge and multi-dose pen injection system. In addition to the development challenges with the novel drug delivery system, the drug formulation and load presented other significant complications. Following this case study, highlights from the new Technical Report on Quality Risk Management for Biopharm manufacturing will be presented. Risk Assessments for typical operations will illustrate the importance and use of this tool in development and helping to proactively address potential processing issues.</p>
<p>1:45 p.m. – 2:15 p.m. Depyrogenation of Combination Products James Cooper, PhD, Consultant, <i>Endotoxin Consulting Services</i></p> <p>2:15 p.m. – 2:45 p.m. Radiation Sterilization of Combination Products John Williams, Senior Manager, <i>Baxter Healthcare</i></p> <p>2:45 p.m. – 3:15 p.m. Q&A</p>	<p>1:45 p.m. – 2:15 p.m. High Titer Production Rolf Douwenga, Vice President, Global R&D, <i>DSM Biologics</i></p> <p>2:15 p.m. – 2:45 p.m. Contract Manufacturing Morten Munk, Vice President CMC, <i>CMC Biologics A/S</i></p> <p>2:45 p.m. – 3:15 p.m. Q&A</p>	<p>1:45 p.m. – 2:15 p.m. Dave Hamilton, Senior Process Engineer, <i>Merck</i></p> <p>2:15 p.m. – 2:45 p.m. Quality Risk Management Case Studies for Biopharm Ruhi Ahmed, PhD, Senior Director, Regulatory Affairs, <i>Ultragenyx Pharmaceutical Inc.</i></p> <p>2:45 p.m. – 3:15 p.m. Q&A</p>

3:15 p.m. – 4:00 p.m.

Refreshment Break, Poster Presentations and Passport Raffle Drawing in Exhibit Hall



Tuesday, April 17, 2012 Agenda (continued)

4:00 p.m. - 5:30 p.m.

Concurrent Interest Groups

<p>IG8 – Facilities and Engineering/ Pharmaceutical Water Systems</p>	<p>Leaders: Christopher Smalley, PhD, Associate Director, BioSterile Validation, <i>Merck</i> Phil DeSantis, Senior Director, Engineering Systems and Compliance, <i>Merck</i></p>	<p>Chris Smalley will introduce the concept of “Green Manufacturing”. The session will be a follow-up to the 2011 PDA/FDA Joint Regulatory Conference Interest Group session, which focused on overall green manufacturing, reducing site energy usage, and implementing solar energy. The topic for the Annual Meeting is “Single Use Systems and Green Manufacturing – Can Disposables Be Green?”</p>
<p>IG9 – Packaging Science</p>	<p>Leader: Edward J. Smith, PhD, Principal Consultant, <i>Packaging Science Resources</i></p>	<p>The Packaging Science Interest Group (PSIG) is a venue for the exchange of knowledge and ideas about pharmaceutical packaging. Members collaborate to develop presentations for PDA programs, organize special meetings on current topics, review USP and FDA proposals and regulations, work on task forces on focused topics, and educate each other. Sessions are held in conjunction with signature PDA meetings.</p>
<p>IG10 – Inspection Trends</p>	<p>Leader: Bob Dana, Senior Vice President of Regulatory Affairs and TRI, <i>PDA</i></p>	<p>The Inspection Trends Interest Group provides a forum for sharing experiences and knowledge in the subject areas. Meeting format varies; we have panel discussions featuring industry and FDA participants, podium presentations on inspection-related activities and programs and an open forum for questions and answers relative to company experiences with government inspections. Data on current inspection findings and trends are presented, as well as discussions on new regulatory and compliance initiatives.</p>
<p>IG11 – Quality Risk Management</p>	<p>Leader: Michael A. Long, PhD, Director, <i>ValSource, LLC</i> Jeffrey Hartman, Validation Manager, <i>Merck</i></p>	<p>Topic: “Mitigating Pharma & BioPharm Equipment Risk Through Human Factors” Companies go to great lengths to ensure that their products and equipment have met various standards, guidelines, technical feasibility and that it leverages the appropriate technology. These same companies institute development design controls and quality management systems to ensure that product requirements have been met and are actualized in the end product. Perhaps, most importantly, a great deal of attention is on mitigating product risk using multiple methodologies such as hazard analyses and failure mode and effects analyses for instance. This same level of rigor, traceability, and risk management is not applied, however, to the human element of the product or equipment. The integration of Human Factors and supporting research is a critical part of developing and maintaining the integrity of user requirements and mitigating any potential use-error risks. This presentation will provide a couple of case studies (e.g. bioreactor, filtration system) in which human factors integration has resulted in equipment design that not only meet product requirements from a technical perspective but also support user requirements in a manner that fosters product compliance while minimizing use-errors.</p> <p>Topic: PCMO initiative on Technical Report Update Discussions</p>

Tuesday, April 17-Wednesday, April 18, 2012 Agenda (continued)

IG12 – Filtration	Leader: Russell E. Madsen, President, <i>The Williamsburg Group, LLC</i>	Russ Madsen will dedicate the Filtration Interest Group session to Theodore (“Ted”) H. Meltzer, PhD, former leader for the PDA Pharmaceutical Water Systems Interest Group. Following a brief tribute to Ted, there will be three (3) fifteen minute presentations from Millipore, Pall and Sartorius-Stedim representatives on the subject of post-sterilization integrity testing. Following those presentations, the session will conclude with a panel discussion with Q&A on pre-filtration bioburden (i.e., the CPMP “requirement” of less than 10 CFU per 100 mL), redundant (serial filtration, and the pros and cons of reusing sterilizing filters.
IG13 – Sterile Processing/ Blow-Fill-Seal	Leaders: Ken H. Muhvich, PhD, Principal Consultant, <i>Micro-Reliance, LLC</i> Chuck Reed, Director, Sales and Marketing, <i>Weiler Engineering</i>	An update will be provided regarding the progress that the Task Force has made in transforming the Blow Fill Seal International Operators Association Guidance Document into a formal PDA Technical Report (TR) on “Sterile Manufacturing using Blow/Fill/Seal (BFS) Technology.” Task Force members will be identified and key points from the Draft Technical Report will be described. Input from attendees is welcome. In addition, aspects of PDA’s updated Aseptic Processing Survey will be discussed.
IG14 – Biotechnology	Leader: Vince Anicetti, Adjunct Professor, <i>Keck Graduate Institute of Applied Life Sciences</i>	The Biotech IG will host an update from the FDA Office of Biotechnology Products (OBP), Steve Kozlowski, PhD, Director, <i>OBP</i> (Invited). The IG will also host task force updates from the Cell and Gene Therapy TF and the Bioburden and Biofilm Management TF.

6:30 p.m. – 9:00 p.m.

Dine Around – When the sky turns from sun to stars, there is nothing like dining in Scottsdale (Optional Event)

Wednesday, April 18, 2012

7:00 a.m. – 1:00 p.m.

Registration Open

7:00 a.m. – 11:15 a.m.

Speaker Ready Room Open

7:00 a.m. – 8:30 a.m.

Continental Breakfast

7:30 a.m. – 8:25 a.m.

Foundations Breakfast Sessions - Building on the success of the Fundamentals Track at the 2011 Annual Meeting, the Program Committee is pleased to make available three breakfast sessions on topics of interest to the Pharmaceutical/Biopharmaceutical community. Each is based on the science outlined in associated PDA Technical Reports and will provide attendees the opportunity to gain foundational knowledge in the topics at hand. Conference attendees wishing to gain a basic awareness or refresh their knowledge of these topics will find these breakfast sessions of value. For those wishing to delve deeper into the topics presented after the sessions, PDA’s Training and Research Institute (PDA TRI) will offer in-depth courses on the subjects later in 2012.



Wednesday, April 18, 2012 Agenda (continued)

Foundations Breakfast Sessions (continued)

Technology	Regulatory	Quality
<p>M – Cleaning Validation for Biotechnology Products Moderator: Michele Creech, Quality Operations Manager, <i>Grifols, Inc.</i></p> <p>This session will describe the essential elements of cleaning validation as they apply to equipment utilized in the manufacture of biotechnology products. Topics such as system design, sampling and analytical techniques, cycle design and establishment of acceptance criteria will be discussed. Principles and techniques to consider for multi-product applications will also be covered.</p>	<p>N – Good Distribution Practices for the Pharmaceutical Supply Chain Moderator: Bob Dana, Senior Vice President of Regulatory Affairs and TRI, <i>PDA</i></p> <p>Knowledge of the impact of environmental conditions on the stability of drug products is essential to the design and control of the supply chain in ensuring the delivery of a quality product to the end user, the patient. This session will focus on the elements important to ensuring the stability of drug products, both small and large molecule, as they move through the distribution chain.</p>	<p>O – Evaluation, Validation and Implementation of New Microbiological Test Methods Moderator: Marsha Hardiman, Senior Manager Corporate Quality Control, <i>Dendreon</i></p> <p>This session will provide a general overview on the introduction of new microbiological test methods in a government-regulated environment. It will discuss ways to ensure the successful evaluation, validation and implementation of new microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. These new methodologies offer significant improvements in terms of the speed, accuracy, precision and specificity with which testing can be performed.</p>
<p>7:40 a.m. – 8:10 a.m. Jenna Carlson, Principal Technical Manager, <i>F. Hoffmann-LaRoche Ltd.</i></p> <p>8:10 a.m. – 8:25 a.m. Q&A</p>	<p>7:40 a.m. – 8:10 a.m. David Ulrich, QA Director/Distribution, <i>Abbott Laboratories</i></p> <p>8:10 a.m. – 8:25 a.m. Q&A</p>	<p>7:40 a.m. – 8:10 a.m. Michael J. Miller, PhD, President, <i>Microbiology Consultants, LLC.</i></p> <p>8:10 a.m. – 8:25 a.m. Q&A</p>

“As usual PDA did not disappoint and once again organized an excellent Annual Meeting, with plenty of time to network, besides presentation tracks, which were filled with highly valuable information and up-dates.”

Maik Jornitz, *Sartorius Stedim NA Inc.*

Wednesday, April 18, 2012 Agenda (continued)

8:30 a.m. – 10:00 a.m.

Concurrent Sessions

Innovation and Productivity in Large Scale Manufacturing	Large Scale Production of Biopharmaceuticals	Control Strategies for Biopharmaceuticals
<p>P – Extractables and Leachables: Packaging Qualification, Quality Performance, and Best Practices Moderator: Wendy Nelson, PhD, Director of Manufacturing, Genentech, Inc.</p> <p>Drug product packaging selection and qualification relies not only on an intended delivery system but also on the type of product formulation. Selection of contact materials, fabrication, assembly and qualification of packaging components are key elements of ensuring quality throughout expiry of the drug product. Qualification of the packaging system is essential to ensuring a safe, reliable and effective drug product and quality performance of the packaging system. Packaging qualification and quality performance will be presented as a part of this session. In addition, this session will focus on regulatory expectations for leachables and extractables in relation to quality risk management and aspects of ICH Q8, 9 and 10 that can be translated to qualification of packaging as well as recommendations for thresholds and best practices for parenterals from the Product Quality Research Institute (PQRI).</p>	<p>Q – Supply Chain Control/Distribution Moderator: Miguel Montalvo, President, Expert Validation Consulting, Inc.</p> <p>This session will discuss adequate procedures and controls for the selection, evaluation, audit, approval and monitoring of critical suppliers in order to protect our product quality attributes and process requirements and the recent developments on Good Distribution Practices requirements. We will review current legislation and guidance in the making pertaining to supplier evaluation and approval and Good Distribution Practice and securing the supply chain. In particular, recent EU legislation changes (proposed Chapter 5 and 7 of the EU GMPs), the World Health Organization guidance on Good Distribution Practices and the EU concept paper on revision of the GDP regulations in Europe.</p>	<p>R – Evolving Regulatory Expectations for Biosimilars Moderator: Phil DeSantis, Senior Director, Engineering Systems and Compliance, Merck</p> <p>In 2009 President Obama signed the Biologics Price Competition and Innovation Act, opening the pathway to licensure of biosimilars in the United States. The European Union had published guidelines in 2005 and approved the first biosimilars as early as 2006. Recently, there has been increasing information exchanged within the industry and in the press about the coming of copies of previously approved biologicals. There is an expectation that the US FDA will publish its own guidance soon, probably before the PDA Annual Meeting. Because of their complex structures, biological molecules cannot be presumed to be exactly the same as their targeted original versions. Seemingly minor differences in structure might have a significant affect on therapeutic properties. The question becomes “How similar is similar enough?” Therefore, the path to approval for these generics will be much more difficult than their small-molecule generic counterparts. Despite the potential time and expense involved in bringing biosimilars to market, the anticipation is that it can be done in a manner which will make these drugs more available and affordable to a broader patient population. Therefore, many companies, both large and small, have thrown their hats into the ring. This session will explore biosimilars from both an industry and a regulatory perspective. As biologics continue to replace small molecules on the list of largest-sellers, where will biosimilars fit in?</p>
<p>8:30 a.m. – 9:00 a.m. E&L Current Best Practices for Packaging and Processing Injectables Ed Smith, PhD, Principal, Packaging Science Resources, LLC</p> <p>9:00 a.m. – 9:30 a.m. Drug Product Contact Materials: Stage Appropriate Assessments for Quality Performance Diane Paskiet, Associate Director of Scientific Affairs, West Pharmaceuticals</p> <p>9:30 a.m. – 10:00 a.m. Q&A</p>	<p>8:30 a.m. – 9:00 a.m. API Evaluation Audit, Approval and Monitoring Amelia Mutere, GMP Compliance, Genentech/Roche Group</p> <p>9:00 a.m. – 9:30 a.m. Good Distribution Practices Karen Ginsbury, Principal, Pharmaceutical Consulting Israel, Ltd.</p> <p>9:30 a.m. – 10:00 a.m. Q&A</p>	<p>8:30 a.m. – 9:00 a.m. Biosimilars Thomas Schreitmueller, Head of Technology and Regulatory Policy, Roche</p> <p>9:00 a.m. – 9:30 a.m. Evolving Regulatory Expectations for Biosimilars FDA Representative (Invited)</p> <p>9:30 a.m. – 10:00 a.m. Q&A</p>

Wednesday, April 18, 2012 Agenda (continued)

10:00 a.m. – 10:30 a.m.

Refreshment Break

10:30 a.m. – 12:00 p.m.

Closing Plenary Session

Moderator: Harold S. Baseman, Chief Operations Officer, *ValSource, LLC*

The health care product industry is facing changes and challenges as a result of innovative products, new technologies, expanded supplier networks, and the growing needs of public health. “Tried and true” traditional methods may not offer the optimal approach to process design, manufacturing, process control, quality assurance, and regulatory compliance. New approaches will be needed. How will the industry and regulators change current approaches in order to meet these new challenges? How can industry and regulators work together to make these changes and develop these new approaches? How can industry and regulators anticipate the challenges they may face and the changes needed to meet those challenges in the future? These and other related issues will be addressed by our distinguished speaker and panel.

10:30 a.m. – 11:00 a.m.

Manufacturing Opportunities and Challenges in the Next 10-20 Years

Matt Croughan, Professor, *Keck Graduate Institute of Applied Life Sciences*

11:00 a.m. – 11:30 a.m.

Emerging Regulatory Expectations

Emily Shacter, PhD, Chief, Laboratory of Biochemistry, CDER, *FDA*

11:30 a.m. – 12:00 p.m.

Q&A

12:00 p.m.

Closing Remarks and Adjournment



Networking Events

It's all about balance so make your conference experience a well-rounded one by participating in networking activities that help jump start your connection with your peers in the industry.

Sunday, April 15, 2012

7:30 a.m. – 12:00 p.m.

6th Annual PDA Golf Tournament at the Wildfire Golf Club – Optional event

Tee it up at the Wildfire Golf Club featuring 36 holes designed by two golf legends, Arnold Palmer and Nick Faldo. Voted “Best Courses You Can Play” by Golfweek Magazine and “America’s Top Golf Courses” by Zagat, come enjoy the scenic views and spacious fairways of the Palmer Signature Course. Team up with your colleagues, friends and family to experience the breathtaking background and take a swing at 18 holes surrounded by the McDowell Mountains.

\$160.00 per person; price includes cart, green fees, practice and range balls, refreshments and lunch.

8:00 a.m. – 10:00 a.m.

PDA's 6th Annual Walk/Run – Optional event – To Benefit the Phoenix Children's Hospital Sponsored by Sartorius Stedim Biotech

On your mark, get set, GO—to the 6th Annual Walk / Run event with your colleagues, family and friends. 100% of your donations go to the Phoenix Children's Hospital and every dollar contributed to the Children's Hospital Foundation has a direct impact on their patients, families, and community, from helping fund clinical programs and support services, to supporting research and injury prevention programs.

Start the week off with your heart rate up, your body energized, and taking in the fresh air at the 3K walk and 5K run through the beautiful grounds of the JW Marriott Desert Ridge Resort.

\$20 per registered attendee or guest; price includes a t-shirt, race bib, snacks and beverages (water, juice, coffee).

Monday, April 16, 2012

7:00 a.m. – 8:00 a.m.

New Member Breakfast (Invitation Only)

Welcome new PDA members! Join us for breakfast to learn more about PDA and to meet other new members, board members and staff.

Monday and Tuesday, April 16-17, 2012

PDA Annual Meeting Career Fair Exhibit/Sponsorship Opportunities

Exhibit at the PDA Annual Meeting Career Fair to interact with highly qualified job seekers from a variety of fields in the biopharmaceutical science and manufacturing industry. With a 10' x 10' booth and dedicated exhibit hall hours, you can showcase your company, employment opportunities, and brand identity to hundreds of attendees seeking to advance their careers. Ample time will be provided for you to solicit resumes, screen candidates, and conduct on site interviews. Sponsoring the PDA Career Fair is an excellent way to generate exposure and recognition for your company. Our sponsorship packages allow you to brand your company as an elite place to work as well as promote company events, products, and services. For more information, please contact David Hall at +1 (240) 688-4405 or hall@pda.org.

Spouse/Guest & Dine Around Programs

Activities have been planned for all to enjoy whether attending the sessions, experiencing a spa treatment, sightseeing activities and the Dine Around planned on Tuesday. To learn more, visit: www.pda.org/annual2012.





Continuing Education



PDA is accredited 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 forms, certificates will be mailed within four to six weeks of the event. Continuing Education Units (CEUs) will be awarded as follows:

2012 PDA Annual Meeting

ACPE #0116-0000-12-025-LO4-P | 1.225 CEUs

Type of Activity: Knowledge

For course CEUs and ACPE information for individual courses, see pages 19-24.

Learning Objectives

Upon completion of this program, you will be able to:

- Discuss the latest technical advances in personalized medicine, cellular therapies and sterile biopharmaceutical manufacturing
- Identify challenges in manufacturing and quality assurance/quality control of sterile products
- Explain current regulatory expectations, philosophies and challenges for manufacturing processes and emerging technologies
- Discuss microbiological control in the manufacturing environment for biopharmaceuticals and advanced aseptic technologies
- Summarize case studies highlighting techniques to plan and implement biopharmaceutical process development, manufacturing, testing and distribution procedures using risk- and science-based approaches, LEAN manufacturing approaches, statistical process control, PAT, etc.
- Identify newly released PDA Technical Reports and use of PDA training programs to improve process development, manufacturing, testing and distribution of sterile products

Who Should Attend

Any and all who are involved in the development, manufacture, testing and distribution of regulated drug and healthcare products – including:

Departments:

- Manufacturing
- Quality
- Research & Development
- Process Development
- Regulatory Affairs
- Engineering
- Laboratory Science
- Information Technology
- Validation
- Training

Job Functions:

- Executive Management
- Mid-level Management
- Project Management
- Technical Services
- Supply Chain
- Manufacturing Application
- Risk Management

And for those new to their job function, we strongly recommend the Foundations Breakfast Sessions.

Specialties:

- Biopharmaceuticals
- Personalized Medicine and Advanced Cellular Therapies
- Biologicals
- Medical Devices
- Active Pharmaceutical Ingredients
- Combination Products
- Nutraceuticals

“It certainly was a great meeting. The agenda was well designed and the flow of sessions, vendor booths, and posters ran smoothly and provided ample opportunity for interesting discussions and interactions.”

Claudio Denoya, *Pfizer Inc.*

2012 PDA Annual Meeting Course Series – April 19-20, 2012

Immediately following the 2012 PDA Annual Meeting, PDA's Training and Research Institute (PDA TRI) will be offering eight courses designed to complement what you've learned at the conference. Six of these courses have never been offered before! These courses will focus on Biotechnology and Bioprocessing, Sterile Dosage Forms, Manual Aseptic Processes, Process Validation and Verification, and more. Get the most out of your experience and receive a discount by registering for both the conference and one or more courses.

Recommended Practices for Manual Aseptic Processes – *New Course!*

April 19, 2012, 8:30 a.m. – 4:00 p.m.

PDA #216 | ACPE #0116-0000-12-216-Lo4-P | 0.6 CEUs

Type of Activity: Knowledge

Course Description

The goal of aseptic processing operations is to prevent the contamination of materials intended to be sterile during these operations. For large scale automated operations where operator interventions are infrequent, the verification of the ability of the process to produce sterile product is evaluated by the conduct of large scale automated media fills in a manner analogous to normal production.

Processes using all or partial manual procedures must also be evaluated by process verification testing; such manual operations present unique operational and evaluation challenges not generally encountered with automated operations. Manual aseptic processes rely heavily on individual operator proficiency; however, operational personnel and their activities are generally recognized as the greatest source of potential microbial contamination during manual aseptic processes. Reproducible human performance cannot be assumed over time.

These and other challenges posed by manual aseptic processing must be considered when designing the evaluation protocol. This course will provide a description of how to address the challenges posed in design, control and evaluation of manual aseptic processing. Topics such as personnel training and qualification, design of manual aseptic processes and evaluation of manual aseptic processing process simulations will be covered. The course is based on a PDA Technical Report addressing the same subject.

This course will provide valuable practical insights into the technological challenges associated with designing, operating and evaluating manual aseptic processing. Participants will come away with an understanding of how manual aseptic processes differ from automated ones, and what should be addressed as they work with manual aseptic processes in their own plants. They will also learn how process simulation testing to evaluate manual aseptic processing operation should be designed and carried out.

Who Should Attend

This course will be of value to operational personnel who design, carry out and evaluate manual aseptic processing, including personnel involved with compounding, filling, packaging, and quality assurance operations. Support staff, such as engineering and validation personnel, will also benefit. The course will be suitable for supervisors and managers as well as personnel engaged in manual processing operations.

Learning Objectives

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

- Discuss the challenges associated with manual aseptic processing
- Describe the elements involved in the design of process simulation studies for manual aseptic processing
- Explain the elements associated with training and qualification of personnel involved with manual aseptic processing
- Explain the differences to be considered when designing manual aseptic processing operations in unidirectional air flow and in isolators
- Apply the lessons learned to the design and conduct of manual aseptic processing operations in your job
- Design a protocol for the conduct of a process simulation test for manual processing

Instructor

TBD

2012 PDA Annual Meeting Course Series (continued)

Reprocessing of Biopharmaceuticals – New Course!

April 19, 2012, 8:30 a.m. – 4:00 p.m.

PDA #158 | ACPE #0116-0000-12-158-Lo4-P | 0.6 CEUs

Type of Activity: Knowledge

Course Description

Occasionally, reprocessing of drug products becomes a necessary activity. There are both technological and regulatory issues which must be addressed when reprocessing becomes necessary. Reprocessing becomes more complicated when biotechnology-derived products are involved. This one day lecture course will provide guidance for the development and execution of reprocessing plans for these types of products. The issues and strategies which need to be considered will be discussed. Case-studies will be used during the course to provide practical examples of the application of the material presented. This course is based on a PDA Technical Report addressing the same subject.

This course will provide practical insights into both the regulatory and technological considerations which must be taken when reprocessing biotechnology-derived products. Participants will come away with an understanding not only of what the considerations are, but how to develop and implement reprocessing plans.

Who Should Attend

This course will be of value to process development, manufacturing, technical service and quality/regulatory affairs staff involved in planning, approving and executing reprocessing plans, including both managers and supervisors in these departments.

Learning Objectives

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

- Identify the pre- and post-approval regulatory reporting considerations and requirements when planning reprocessing strategies for biotechnology-derived products
- Describe the contents of post-approval regulatory submissions for reprocessing of biotechnology-derived products
- Explain the difference between proactive and reactive reprocessing

- Discuss the requirements of investigations associated with reprocessing
- Create appropriate procedures governing reprocessing
- Apply the lessons learned from case studies of actual reprocessing activities to reprocessing operations in your job

Instructor

TBD

Biotechnology: Overview of Principles, Tools, Processes and Products

April 19-20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #279 | ACPE #0116-0000-10-279-Lo4-P | 1.2 CEUs

Type of Activity: Knowledge

Course Description

Biotechnology is the use of biological processes and components to provide useful products, services and tools for a variety of applications. It uses knowledge from a variety of disciplines such as molecular biology, biochemistry, chemistry, microbiology, chemical engineering and computing. This course is designed to provide biotechnologists and non-biotechnologists with a basic understanding of the theory, principles, techniques and potential of this rapidly moving field.

Topics covered include: scientific principles, overview of tools (recombinant DNA, genomics and gene arrays, proteomics, bioinformatics, etc.), biopharmaceutical product development, biomanufacturing strategies (protein expression, fermentation, cell culture, downstream processing and purification), and types of products and their applications in medicine. The course format includes a combination of lecture with interactive group discussions.

Who Should Attend

Managers, group leaders, supervisors, scientists and technicians from R&D and manufacturing units in biotech organizations who need an integrated overview of the field; Engineering/Validation and Quality Control/Quality Assurance staff persons moving into the biotechnology field; Career changers interested in learning the fundamentals of the biotechnology industry; Lawyers, architects and other individuals with limited background in biotechnology who work on biotech projects.

2012 PDA Annual Meeting Course Series (continued)

Learning Objectives

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

- Define biotechnology and understand current applications of biotechnology and its products in the biopharmaceutical industry
- Discuss the fundamental tools and how they are used in biotechnology
- Explain the biopharmaceutical product and process development steps
- Describe the key steps in typical biopharmaceutical manufacturing processes

Instructor

Antonio Moreira, PhD, Vice Provost for Academic Affairs,
University of Maryland Baltimore County

Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotechnology Manufacturing Operations – *New Course!*

April 19-20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #224 | ACPE #0116-0000-12-224-Lo4-P | 1.2 CEUs
Type of Activity: Knowledge, Application

Course Description

Modern quality systems utilize the principles of quality risk management to strengthen the decision-making process. This course will provide detailed guidance for application and implementation of quality risk management principles throughout the product lifecycle, with emphasis on quality risk management application during commercial manufacturing, and integrating quality risk management into the Pharmaceutical Quality System. The course will build on the content and principles of ICH Q9, Quality Risk Management. The application of quality risk management will be discussed from a lifecycle approach, from pharmaceutical development to technology transfer, commercial manufacturing and product discontinuation, and will include materials management and contract services. Case study examples of quality risk management application will be given for different types of manufacturing operations such as biotech API manufacturing, drug product manufacturing, packaging and labeling. This course is based on PDA Technical Reports addressing these subjects.

Who Should Attend

Managers and supervisors in manufacturing, technology transfer, quality assurance and regulatory affairs will benefit from this course.

Prerequisites

A basic understanding of risk management principles and risk management tools will be helpful to participants in this course.

Learning Objectives

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

- Describe when, where, and how to apply quality risk management throughout the product lifecycle with emphasis on commercial manufacturing
- Plan quality risk management activities
- Execute risk assessments and develop an overall strategy for the use of different risk assessment tools
- Establish a quality risk management policy and implement the essential elements for risk management in your organization
- Apply the principles learned to conduct risk management activities for a variety of product-related and operational decisions in your job

Instructors

Jeffrey Hartman, Validation Manager, *Merck*
Emma Ramnarine, Head, Global Quality Risk Management,
F. Hoffman-LaRoche Ltd.

2012 PDA Annual Meeting Course Series (continued)

Process Validation and Verification: A Lifecycle Approach – *New Course!*

April 19-20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #320 | ACPE #0116-0000-12-320-Lo4-P | 1.2 CEUs

Type of Activity: Knowledge

Course Description

The FDA has updated its recommendations to the traditional process validation program to encompass a new lifecycle approach. This course is designed to explain and facilitate the implementation of Process Validation (PV) and Continued Process Verification (CPV) from a practical perspective. The three stages of process validation activities will be addressed, from the design stage through commercial production. Statistical methods will be discussed along with the stages where they are most commonly used. There will be application of modern risk management and quality system tools and concepts. Other topics include Process Analytical Technology (PAT), Technology Transfer and Scale-Up, and Documentation/Knowledge Management. This course is based on a PDA Technical Report addressing the same subject.

Expectations for what is required to demonstrate that a manufacturing process has been and remains in a state of validation have changed dramatically with the publication of FDA's Process Validation Guidance. This course will provide participants with the knowledge they need to ensure that process validation strategies and approaches are consistent with current regulatory and quality system thinking. Attendees will be able to apply these concepts when they return to their jobs.

Who Should Attend

This course will be of value to individuals responsible for the design, execution and evaluation of validation strategies and activities. This includes managers and supervisors in operations, validation, engineering, statistics, quality assurance and regulatory affairs.

Learning Objectives

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

- Explain the progression of lifecycle activities
- Interpret the three stages of process validation
- Utilize risk assessment and management tools for the process validation lifecycle
- Demonstrate Continued Process Verification
- Utilize statistical analysis tools
- Apply the concepts learned to the design, implementation and evaluation of process validation and verification strategies and activities in your job

Instructor

Scott Bozzone, PhD, Sr. Manager in Quality Systems Technical Services – Validation, *Pfizer, Inc.*

Sterile Pharmaceutical Dosage Forms

April 19-20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #352 | ACPE #0116-0000-11-352-Lo4-P | 1.2 CEUs

Type of Activity: Knowledge

Course Description

This introductory two-day course on sterile dosage forms will address clean room facilities, environmental monitoring and control, sterilization principles, manufacturing unit operations, aseptic filling, dosage form development, packaging & stability requirements, validation of aseptic processing and product specific validation, QA/QC for parenterals, and regulatory trends.

Who Should Attend

The course is designed to provide a broad overview for individuals working in sterile manufacturing, QA/QC, microbiology, formulation development, package engineering, and compliance training.

2012 PDA Annual Meeting Course Series (continued)

Learning Objectives

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

- Describe product specific validation for parenteral dosage forms
- Discuss aspects of dosage form development, packaging and stability
- Describe the chemical composition of endotoxins, their toxic effects, source and testing procedures
- Summarize the current cGMP regulatory and inspection trends for parenteral manufacturing

Instructor

John Ludwig, PhD, Executive Director, Pfizer Inc.

Investigating Microbiological Data Deviations – New Course!

April 20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #441 | ACPE #0116-0000-12-441-L04-P | 0.6 CEUs
Type of Activity: Knowledge

Course Description

Out of Specification (OOS) test results are sometimes encountered during analytical testing of drug substances and products. Existing FDA guidance addresses the investigation of OOS test results, but is silent on the subject of data deviations encountered in microbiological testing. However, these are often encountered in pharmaceutical quality control laboratories. This course will provide a practical approach which may be applied globally for the investigation of microbiological data deviations.

The roles of manufacturing, the testing laboratory and Quality Assurance will be considered, and fundamental elements to be addressed in writing reports summarizing those investigations will be covered. Flowcharts, checklists and process flow diagrams will be utilized to illustrate the concepts presented. This course is based on a PDA Technical Report addressing the same subject.

This course will provide practical insights into both the regulatory and scientific considerations which must be taken when investigating microbiological data deviations. Participants will come away with an understanding not only of what the considerations are, but a practical approach of how to design and conduct these investigations.

Who Should Attend

This course will be of value to quality control staff who conduct and assess the results of microbiological testing. It will also be of benefit for quality control and quality assurance staff who conduct investigations into microbiological data deviations and write and approve reports of those investigations. Analysts, laboratory supervisors and managers and quality assurance staff will all benefit from this course.

Learning Objectives

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

- Identify microbiological test results which deviate from anticipated results and trends
- Explain the responsibilities of laboratory, manufacturing and quality assurance staff in preparing for, conducting, reviewing and documenting investigations into microbiological data deviations
- Describe the essential elements of reports of investigations into microbiological data deviations
- Discuss the benefits of flowcharts, checklists and process flow diagrams as they apply to the investigation process
- Apply the concepts learned in situations involving microbiological data deviations when necessary in your daily job.

Instructor

TBD

PDA TRI Class Schedule

- 8:30 a.m. – 10:00 a.m. Classroom activity
- 10:00 a.m. – 10:15 a.m. Break
- 10:15 a.m. – 12:00 noon Classroom activity
- 12:00 p.m. – 1:00 p.m. Lunch (provided)
- 1:00 p.m. – 2:30 p.m. Classroom activity
- 2:30 p.m. – 2:45 p.m. Break
- 2:45 p.m. – 4:00 p.m. Classroom activity

2012 PDA Annual Meeting Course Series (continued)

Process Simulation Testing for Aseptically Filled Products – *New Course!*

April 20, 2012, 8:30 a.m. – 4:00 p.m.

PDA #374 | ACPE #0116-0000-12-374-Lo4-P | 0.6 CEUs

Type of Activity: Knowledge

Course Description

The goal of aseptic processing operations is to prevent the contamination of materials intended to be sterile during these operations. The verification of the ability of the process to produce sterile product is evaluated by the conduct of large scale automated process simulation testing (media fills). This course, which is based on a recently revised PDA Technical Report addressing the same subject, will address all the various elements required in the design and execution of a media fill, including personnel qualification, media selection and preparation, filling considerations, interventions, duration and number of units filled, pre and post incubation inspections, incubation conditions, acceptance criteria and investigations and corrective actions. The use of risk-based decision making will be considered.

Process simulation testing is expected as part of a firm's quality system to ensure the sterility of products manufactured using aseptic processing techniques. Participants in this course will come away with an up to date understanding of current scientific and regulatory advances in the design, conduct and interpretation of process simulations. The knowledge they gain can be applied immediately to media fill operations in their own jobs.

Who Should Attend

This course will be of value to managers and supervisors involved in the design, operation, evaluation and approval of process simulation testing. This includes persons working in operations, quality assurance, microbiology, and regulatory affairs. Individuals in facility engineering will also benefit from attendance.

Prerequisites

Individuals taking this course should have a basic understanding of aseptic manufacturing operations. This is not a course designed to teach the basic fundamentals of aseptic processing.

Learning Objectives

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

- Identify the updated scientific and regulatory technology and expectations in the design, operation and interpretation of process simulations
- Discuss process simulation concepts and principles such as the number and frequency of simulations, worst case and risk assessment and ongoing evaluations
- Describe how to use risk management as it applies to aseptic processing simulations
- Discuss how process simulations can be applied to various types of aseptically processed products (lyophilized products and powders)
- Explain why environmental monitoring is an important element of process simulations
- Discuss the necessary documentation associated with process simulations
- Apply modern concepts to establish appropriate acceptance criteria for media fills, evaluate the results and as necessary investigate any failures and recommend appropriate corrective and preventive actions

Instructor

Harold Baseman, Principal, *ValSource, LLC* and Task Force Co-Leader of *PDA Technical Report 22 (Revised 2011)*; *Process Simulation for Aseptically Filled Products*

For additional information about the 2012 PDA Annual Meeting training courses, contact:

Stephanie Ko

Senior Manager, Lecture Education

Tel: +1 (301) 656-5900 ext. 151

E-mail: ko@pda.org

For registration inquiries please call:

+1 (301) 656-5900 ext. 115

General Information

Three Ways to Register

1. Click www.pda.org/annual2012
2. Fax +1 (301) 986-1093
3. Mail PDA Global Headquarters
Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA

Venue

JW Marriott Desert Ridge Resort

5350 East Marriott Drive
Phoenix, Arizona 85054
Phone: +1 (480) 293-5000
Fax: +1 (480) 293-3600
Toll-Free: +1 (800) 835-6206
www.jwdesertridgeresort.com

Rate: Single \$264.00 plus applicable state and local taxes.

Cut Off Date: Friday, March 23, 2012
Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the conference rate.

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

Conference Registration Hours

Sunday, April 15
2:00 p.m. – 6:00 p.m.

Monday, April 16
7:00 a.m. – 5:30 p.m.

Tuesday, April 17
7:30 a.m. – 5:45 p.m.

Wednesday, April 18
7:00 a.m. – 1:00 p.m.

TRI Course Registration Hours

Thursday, April 19
7:30 a.m. – 4:00 p.m.

Friday, April 20
7:30 a.m. – 4:00 p.m.

Dress/Attire

Business casual attire is recommended for the 2012 PDA Annual Meeting. 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

Conference inquiries:
Wanda Neal, CMP
Senior Vice President,
Programs and Registration Services
Phone: +1 (301) 656-5900 ext. 111
E-mail: neal@pda.org

Registration inquiries:
Patresa Day
Manager of Registration
and Customer Service
Phone: +1 (301) 656-5900 ext. 115
E-mail: day@pda.org

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

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



2012 PDA ANNUAL MEETING

April 16-18, 2012 • JW MARRIOTT DESERT RIDGE RESORT • PHOENIX, ARIZONA

EXHIBITION: APRIL 16-17 | POST-CONFERENCE WORKSHOP: APRIL 18-19 | COURSES: APRIL 19-20

Registration for the 2012 PDA Annual Meeting is fast and simple... **CLICK, FAX OR MAIL:**

CLICK: www.pda.org/annual2012 • FAX: +1 (301) 986-1093 (USA)

MAIL: PDA Global Headquarters, 4350 East West Highway, Suite 150, Bethesda, MD 20814 USA

1 Contact Information

PDA Membership Number: _____

Prefix _____ Name (Last, First, MI) _____

Job Title _____

Department _____ Company _____

Mailing Address _____

City _____ State/Province _____ ZIP+4/Postal Code _____

Country _____ Email _____

Business Phone _____ Fax _____

Substituting for

(Check only if you are substituting for a previously enrolled colleague; the fee difference in the prevailing rate is due at the time of substitution. Please note that if you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee.)

2 Conference Registration | April 16-18, 2012 Please check appropriate fee (US\$).

	Member		Nonmember		Government/Health Authority		Academic		Student	
	Member	Nonmember	Member	Nonmember*	Member	Nonmember*	Member	Nonmember*	Member	Nonmember*
Before February 3, 2012	<input type="radio"/> \$ 1,495	<input type="radio"/> \$ 1,744	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 695	<input type="radio"/> \$ 795	<input type="radio"/> \$ 225	<input type="radio"/> \$ 285		
February 3 – March 6, 2012	<input type="radio"/> \$ 1,695	<input type="radio"/> \$ 1,944	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 775	<input type="radio"/> \$ 875	<input type="radio"/> \$ 280	<input type="radio"/> \$ 310		
After March 6, 2012	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 2,144	<input type="radio"/> \$ 700	<input type="radio"/> \$ 800	<input type="radio"/> \$ 860	<input type="radio"/> \$ 960	<input type="radio"/> \$ 315	<input type="radio"/> \$ 345		
Single Use Systems Workshop April 18-19 – Workshop Only	<input type="radio"/> \$ 700									
Single Use Systems Workshop April 18-19 – Workshop and Full Conference Purchase	<input type="radio"/> \$ 550									

* For Government, Academic, Health Authority and Student nonmember registrations, you must mail or fax this form to PDA. Please note: In order to receive the prevailing registration rate, your registration(s) with payment must be received by PDA by 5:00 p.m. ET on or before the date noted.

See the [registration fees online](#) for pricing on networking events, group registration discounts and information on the spouse program.

April 17, 2012 - 7:30 a.m. - 8:30 a.m.

Breakfast Session: Career Development Strategies

Included in Registration I will attend.

3 Networking Registration

6th Annual Walk/Run – Sponsored by Sartorius Stedim Biotech Sunday, April 15, 2012, 8:00 a.m. – 10:00 a.m. (Registration includes: Access to walk/run, t-shirt, race bib, snacks and beverages. 100% of the registration fees are donated to the Phoenix Children's Hospital.)	<input type="radio"/> \$20
PDA 6th Annual Golf Tournament Sunday, April 15, 2012, 7:30 a.m. – 12:00 p.m. For more details please visit the networking page of the Annual Meeting website www.pdaannualmeeting.org/networking-events . (Registration includes: Golf cart, practice and range balls, green fees, refreshments and lunch)	<input type="radio"/> \$160

4 PDA/TRI Course Registration

	Price on or before March 6, 2012				Price after March 6, 2012			
	Standard		Government/Health Authority/ Academic		Standard		Government/Health Authority/ Academic	
	Member	Nonmember	Member	Nonmember	Member	Nonmember	Member	Nonmember
#158 Reprocessing of Biopharmaceuticals (April 19)	<input type="radio"/> \$ 895	<input type="radio"/> \$ 1,165	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700	<input type="radio"/> \$ 995	<input type="radio"/> \$ 1,295	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700
#216 Recommended Practices for Manual Aseptic Processes (April 19)	<input type="radio"/> \$ 895	<input type="radio"/> \$ 1,165	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700	<input type="radio"/> \$ 995	<input type="radio"/> \$ 1,295	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700
#279 Biotechnology: Overview of Principles, Tools, Processes and Products (April 19-20)	<input type="radio"/> \$ 1,435	<input type="radio"/> \$ 1,705	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050	<input type="radio"/> \$ 1,595	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050
#224 Implementation of Quality Risk Management for Commercial Pharmaceutical and Biotechnology Manufacturing Operations (April 19-20)	<input type="radio"/> \$ 1,435	<input type="radio"/> \$ 1,705	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050	<input type="radio"/> \$ 1,595	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050
#352 Sterile Pharmaceutical Dosage Forms (April 19-20)	<input type="radio"/> \$ 1,435	<input type="radio"/> \$ 1,705	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050	<input type="radio"/> \$ 1,595	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050
#320 Process Validation and Verification: A Lifecycle Approach (April 19-20)	<input type="radio"/> \$ 1,435	<input type="radio"/> \$ 1,705	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050	<input type="radio"/> \$ 1,595	<input type="radio"/> \$ 1,895	<input type="radio"/> \$ 950	<input type="radio"/> \$ 1,050
#374 Process Simulation Testing for Aseptically Filled Products (April 20)	<input type="radio"/> \$ 895	<input type="radio"/> \$ 1,165	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700	<input type="radio"/> \$ 995	<input type="radio"/> \$ 1,295	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700
#441 Investigating Microbial Data Deviations (April 20)	<input type="radio"/> \$ 895	<input type="radio"/> \$ 1,165	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700	<input type="radio"/> \$ 995	<input type="radio"/> \$ 1,295	<input type="radio"/> \$ 600	<input type="radio"/> \$ 700

2012 PDA ANNUAL MEETING

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EXHIBITION: APRIL 16-17 | **POST-CONFERENCE WORKSHOP:** APRIL 18-19 | **COURSES:** APRIL 19-20
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5 Total Registration Fees

Conference *	\$
Post-conference Workshop	\$
Networking Events	\$
Course(s) *	\$
Course and Conference Registration Discount <-\$150> *	\$
TOTAL	\$

* Attendees receive a \$150 discount when they register for both the conference and a course.

6 Payment Options All cards are charged in US\$.

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

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

Total amount \$ _____

Account Number _____

Exp. Date _____

Name (exactly as it appears on card) _____

Signature _____

Billing address _____

City _____

State _____

Zip _____

Country _____

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

PDA Federal Tax I.D. #52-1906152

Special Dietary Requirements (Please be specific): _____

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 requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancellation notice is not received by **February 16, 2012** 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 pre-registered as a substitute attendee, indicate this on the registration form. The fee difference in the prevailing rate is due at the time of substitution. Please note that if you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Conference/Event:** If your written request is received on or before **February 16, 2012**, 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 by **March 20, 2012**, you will receive a full refund less a \$200 processing fee. After that time, no refunds or credit approvals will be made. **EVENT/COURSE CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be cancelled, registrants will be notified by PDA in writing 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@pda.org or +1 (301) 656-5900.

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



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*Manufacturing Innovation: Achieving Excellence
 in Sterile and Emerging Biopharmaceutical Technology*



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Exhibition and Sponsorship Opportunities

The 2012 PDA Annual Meeting will provide your company the premier opportunity to gain access to and network with key decision makers from the biopharmaceutical science and manufacturing industry. Find new customers, discuss ongoing projects, discover new opportunities, and reconnect with current customers by exhibiting at or sponsoring the industry's leading conference and exhibition. Extended, dedicated exhibit hall hours will allow ample time for information exchange with attendees and industry subject matter experts from companies such as Genentech, Eli Lilly, Pfizer, Amgen, GlaxoSmithKline, Abbott, Roche, Novartis, Merck and others. This meeting will bring together all levels of industry professionals and regulators who will benefit from a program that focuses on new technologies and manufacturing innovation. Attendees will include industry professionals from manufacturing, quality, research & development, process development, risk management, regulatory affairs, engineering, laboratory science, validation, information technology, and supply chain management. Many high profile, cost-effective sponsorship options are available to help your company increase exposure, build awareness, and stand out from the crowd. Become a sponsor and/or exhibit at the 2012 PDA Annual Meeting and strengthen your brand image, increase your visibility, and gain access to hundreds of leaders in the industry.

"It was a great opportunity to learn about new trends in the parenteral field. I was able to find out possible third party labs for forensic analysis as well as for identification."
 Jaime Valdez, BD

Preliminary
 Agenda
 Inside

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

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EXHIBITION: April 16-17 | **CAREER FAIR:** APRIL 16-17 | **POST-CONFERENCE WORKSHOP:** April 18-19 | **COURSES:** April 19-20