The Parenteral Drug Association presents the...

2016 PDA Annual Meeting

Harness the Power of Innovation to Improve Access to Novel Therapies

March 14-16, 2016 | San Antonio, TX

JW Marriott San Antonio Hill Country

Exhibition: March 14-15

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Achieving Manufacturing Excellence: Current Trends and Future Technologies in Bioprocessing

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#2016Annual

Preparing for the Next Generation of Regulatory Inspections: A 2016 PDA Manufacturing Science Workshop: March 16-17

See page 18 for details

Courses: March 17-18

This preliminary agenda is current as of October 30, 2015

TAPE RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS

PROGRAM PLANNING COMMITTEE

Program Co-Chairs:

Michael DeFelippis, PhD
Eli Lilly & Company

Maik Jornitz
G-Con Manufacturing, Inc.

Vijay Chiruvolu, PhD
Kite Pharma

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Pfizer, Inc.

Ghada Haddad
Merck & Company, Inc.

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Steven Lynn, MS, CMQ/OE
Novartis Services, Inc.

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Susan Schniepp
Regulatory Compliance Associates, Inc.

Jean Stanton
Johnson & Johnson

Glenn Wright
Eli Lilly & Company

Jason Brown
Liaison to the Committee
PDA

Wanda Neal, CMP
Liaison to the Committee
PDA

A MESSAGE FROM THE PROGRAM CHAIRS

Michael DeFelippis, PhD
Eli Lilly & Company

Maik Jornitz
G-Con Manufacturing, Inc.

Dear Friends, Colleagues and Peers,

As the Co-Chairs of the Program Planning Committee, we invite you to attend the *2016 PDA Annual Meeting* taking place in San Antonio, TX at the JW Marriott San Antonio Hill Country Resort & Spa March 14-16, 2016.

The rapid pace of scientific discoveries in medical research has placed unprecedented demands on the development and manufacturing capabilities of the pharmaceutical industry. The number of new biopharmaceuticals and molecular entities entering clinical evaluation continues to increase annually. Personalized medicine is likewise becoming a reality with the emergence of gene and cell therapies. Additionally, issues such as globalization, patient access, emerging markets and world health epidemics are further challenging our industry. How is industry currently responding to this situation and what is needed to ensure sustained delivery of pharmaceutical innovation? These questions were thoughtfully considered in selecting the theme for the *2016 PDA Annual Meeting – Achieving Manufacturing Excellence: Current Trends and Future Technologies in Bioprocessing.*

The Program Planning Committee has worked diligently over the past several months to develop a comprehensive and informative conference program. A wide variety of presentation topics are included, which are of critical interest to all of us. You can select from the array of in-depth presentations and have the opportunity to meet with the subject matter experts and your peers. This face-to-face communication is invaluable to gain robust information and answers to your specific questions.

Keynote speakers will focus on putting the patient first and discuss accelerated development, personalized treatments, breakthrough therapies, Ebola vaccines, market access, manufacturing of the future and continuous bioprocessing. Concurrent session tracks will address upstream and downstream process technology innovations, monitoring and optimization. The manufacturing sciences track is designed to inform about facility improvements, multi-purpose/multi-product facilities, new single-use process technologies and their verification and the supply chain needs for personalized medicines. Other topics discussed are the application of QRM in cell therapies, product and process lifecycle management and analytical technologies utilized in continuous manufacturing streams.

The conference program topics are further supported by interactive interest group meetings and breakfast sessions, which you can tailor to your needs. And, if you want even more detailed knowledge on topics presented at the *2016 PDA Annual Meeting*, please consider attending one of the many PDA Education courses.

On behalf of the Program Planning Committee, the presenters, exhibitors and the PDA team, we look forward seeing you in San Antonio!

GENERAL INFORMATION, REGISTRATION

Four Ways to Register

1. **CLICK** **pda.org/2016annual**
2. **FAX** +1 (301) 986-1093
3. **MAIL** PDA Global Headquarters
   Bethesda Towers
   4350 East West Highway, Suite 150
   Bethesda, MD 20814 USA
4. **PHONE** +1 (301) 656-5900 ext. 115

Venue

JW Marriott San Antonio Hill Country Resort & Spa
23808 Resort Parkway, San Antonio, TX USA 78261
Phone: +1 (210) 276-2500 | Website: www.jwsanantonio.com

Rate: Single/Double: $269, plus 16.75% state and local taxes. If making your reservation via phone, reference the *2016 PDA Annual Meeting* to ensure you receive the correct rate.

Cut Off Date: Friday, February 12, 2016 (A block of rooms is available for PDA attendees on a first come basis and must be secured by the cut-off date to receive the PDA rate). After the cut-off date, rooms will be available at the prevailing rate based on availability.

Continuing Education Credits

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

2016 PDA Annual Meeting
CPE: ACPE # 0116-0000-15-016-L04-P | 1.3 CEUs
Type of Activity: *Knowledge*

Learning Objectives
At the completion of this conference, you will be able to:

- Describe current trends in upstream and downstream process development and assess utility of future technology applications in pharmaceutical and biopharmaceutical processing
- Summarize manufacturing needs required to process and supply novel cell therapies and personalized medicines
- Explain approaches to mitigate supply chain risks for biopharmaceuticals and cell therapies and define effective strategies for implementation
- Describe practical solutions for using analytical control systems, product and process monitoring information to successfully drive continuous improvement over the product lifecycle
- Interpret the current issues with microbiological and adventitious agent control strategies and identify strategies to mitigate risks
- Identify best practices for successful technology transfers and application of data to support process validation
- Explain approaches to increase global access to medicines and describe industry response strategies to worldwide health crises like Ebola

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 | Operations

Conference Registration Hours

Sunday, March 13: 3:00 p.m. – 6:00 p.m.
Monday, March 14: 7:00 a.m. – 5:15 p.m.
Tuesday, March 15: 7:00 a.m. – 5:15 p.m.
Wednesday, March 16: 7:00 a.m. – 12:00 p.m.

Workshop Registration Hours

Wednesday, March 16: 12:00 p.m. – 5:00 p.m.
Thursday, March 17: 7:30 a.m. – 5:00 p.m.

Course Registration Hours

Thursday, March 17: 7:30 a.m. – 4:00 p.m.
Friday, March 18: 7:30 a.m. – 4:00 p.m.

Dress/Attire

Business casual attire is recommended for the *2016 PDA Annual Meeting*. Since the temperature in meeting rooms tend 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 registration@pda.org.

Contact Information

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PDA Parenteral Drug Association

Connecting People, Science and Regulation®

SUNDAY, MARCH 13 – MONDAY, MARCH 14, 2016 AGENDA

SUNDAY, MARCH 13, 2016

7:00 a.m. – 10:00 a.m.
10th Annual Walk/Run Event – Benefiting Fisher House *(Optional Event, see page 17 for more information)*

7:00 a.m. – 12:00 p.m.
PDA Golf Tournament *(Optional Event, TPC San Antonio Golf Course, see page 17 for more information)*

3:00 p.m. – 6:00 p.m.
Registration Open

3:00 p.m. – 6:00 p.m.
Speaker Ready Room Open

6:30 p.m. – 9:30 p.m.
PDA Awards Dinner *(Invitation Only)*

MONDAY, MARCH 14, 2016

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

7:00 a.m. – 5:15 p.m.
Speaker Ready Room Open

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

8:00 a.m. – 8:30 a.m.
Welcome and Opening Remarks
Martin VanTrieste, Senior Vice President, Quality, *Amgen, Inc.,* and Chair, PDA Board of Directors
Richard Johnson, President & CEO, *PDA*
Maik Jornitz, President, *G-Con Manufacturing, Inc.,* and Co-Chair, *2016 PDA Annual Meeting* Program Planning Committee

8:30 a.m. – 10:00 a.m.
P1 – Opening Plenary Session: Putting the Patient First
Moderator: Maik Jornitz, President, *G-Con Manufacturing, Inc.*

Session Description: Patients are our foremost focus of our daily work, of our quality principles and our joined activities. It is of importance to hear and learn from patients and it is of importance to see progress in other innovative treatment options. This session focuses on the patients and new treatment options, which save lives.

8:30 a.m. – 9:00 a.m.
Patient Perspective
Dave deBronkart, Co-Founder & Co-Chair, *Society of Participatory Medicine*

9:00 a.m. – 9:30 a.m.
Accelerating Innovation to the Patient
Marina Kozak, PhD, Science Policy Analyst, *Friends of Cancer Research*

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

9:45 a.m. – 6:45 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall

MONDAY, MARCH 14, 2016 AGENDA (CONTINUED)

10:45 a.m. – 12:15 p.m.
P2 – Manufacturing and Supply Considerations to Enable Novel Therapies
Moderator: Ghada Haddad, Director, Engineering, Sterile & Validation, *Merck & Company, Inc.*

Session Description: Novel therapies are in fact novel because they are unique and innovative. Once they become mainstream, as with monoclonal antibodies targeting tumor necrosis factor-alpha, many of the issues associated with their manufacture and distribution need to be substantially resolved. But while they are novel, the batch sizes are small, the distribution pathways are individualized and a myriad of other issues pose challenges to their development and introduction.

Many times, these circumstances are so unique that the ICH S6 guidance is sometimes known as the case-by-case approach. What might have worked for one novel therapeutic might not be able to be leveraged and optimized for the next. However, there are approaches to addressing the highly complex manufacturing processes, difficulty in not only developing an appropriate analytical method but also in achieving accuracy with the method, the sensitivity to light, heat, shaking and other phenomena encountered during preparation and distribution, among others which all can be tackled in a scientific and robust manner.

Our first presentation will be about a novel approach to commissioning, qualification, and validation of facilities, utilities and equipment for a new therapy in a new facility. Our second presentation will address the complexities associated with collecting, modifying and returning to the same patient autologous cell therapies, knowing that timing is crucial to both the product and the patient. How can we adapt the concepts of assay and batch release, sterility testing and the other classic GMP systems to novel therapies?

10:45 a.m. – 11:15 a.m.
Enhancing Compliance through Novel Approaches to Commissioning & Qualification/Validation (CQV) of Facilities, Utilities & Equipment Systems Used in Biologics Manufacturing
Brian Urban, Senior Manager, Validation, *Biogen Idec, Inc.*
Tolga Musa, Associate Director, Process Engineering, *Biogen Idec, Inc.*

11:15 a.m. – 11:45 a.m.
Developing a Supply Chain for Autologous Cell Therapy Products
Michele Myers, PhD, Director CMC, Advanced Therapy Delivery, Biopharm R&D, *GlaxoSmithKline*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.
Networking Luncheon in Exhibit Hall

1:45 p.m. – 3:15 p.m.
Concurrent Sessions

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A1 – Achieving High Quality and Productivity in Cell Culture Processes **Moderator: Michael DeFelippis, PhD,** Senior Research Fellow, *Eli Lilly & Company*	**B1 – Ensuring Supply by Using Multiproduct Facilities and Reducing Supply Chain Risk** **Moderator: Vijay Chiruvolu, PhD,** Senior Director, Product Sciences, *Kite Pharma*	**C1 – Integrating New Technologies and Products: Processes and Tools for Managing Decisions and Execution** **Moderator: Jean Stanton,** Director, Regulatory Compliance, *Johnson & Johnson*
Session Description: With the explosive growth in biopharmaceutical candidates entering various stages of clinical development and being commercialized, along with significant advances in cell therapies, the industry is continually exploring novel approaches for reducing time to market, maintaining cost effectiveness	**Session Description:** Preventing and mitigating drug shortages is a top priority for FDA and therefore the industry. Drug supply disruptions can occur due to factors that are under the control of the manufacturers or reasons unforeseen. The likelihood of drug shortages for biologics may be high since they are produced	**Session Description:** Innovation for the purpose of improved productivity is a primary driver for many current biopharmaceutical trends. The top trends related to innovation center around downstream process improvement, single use implementation, analytical methods, cost reductions and product platforms.

MONDAY, MARCH 14, 2016 AGENDA (CONTINUED)

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A1 – Achieving High Quality and Productivity in Cell Culture Processes *(continued)*	**B1 – Ensuring Supply by Using Multiproduct Facilities and Reducing Supply Chain Risk** *(continued)*	**C1 – Integrating New Technologies and Products: Processes and Tools for Managing Decisions and Execution** *(continued)*
and providing robust manufacturing capability in an ever-increasingly competitive landscape. These realities have driven significant investments in process development to meet demand for greater output from cell cultures while simultaneously reducing variability to ensure the highest possible product quality. For example, advances in mammalian cell culture processes for biopharmaceuticals over the last 20 years have resulted in tremendous increases in product concentration with titers now routinely reaching 5 g/L. Cell culture medium optimization is considered a recent key factor in realizing these improvements. In parallel with these productivity achievements came understanding of the critical importance of raw materials utilized in cell culture. Raw material selection and control is paramount to maintaining the health of cells and reducing variability ensuring ultimate product quality. These same raw material considerations apply to cell therapies as well. While productivity and quality are desired, the high cell densities achieved in biopharmaceutical manufacturing can place increased burden on other operations such as cell retention particularly in perfusion processes and novel alternatives to filter systems are being evaluated. This session focuses on current strategies and new technologies for cell culture processes with emphasis on approaches for optimizing product output and ensuring quality.	in living cells, require complex manufacturing processes and rigorous regulatory compliance and are sensitive to storage and shipping conditions. Driven by cost pressures, the biopharmaceutical manufacturing paradigm is shifting from large, single-product facilities to smaller-scale, flexible, multiproduct facilities that are cheaper to build. These facilities enable flexible, multiproduct production using single-use technologies, continuous processing and modular designs. Similarly, autologous cell therapy products are made in multi-patient facilities that utilize single-use technologies and rely on manual aseptic operations. In addition, the challenges faced by supply chain are enormous due the need for traceability and a shorter product shelf life. This session focuses on use of risk management and innovations in technology to reduce supply disruptions and shortages.	A timely, cost-effective method to evaluate new technologies is critical to an organization's return on investment for such a process. A number of biopharmaceutical organizations have developed some type of process by which to analyze the technical and operational need for an appraisal, tools to assist with data collection for the decision making process and a way to implement the new technology. This presentation will highlight a decision matrix tool for the appraisal of a new technology as well as a governance model for the evaluation, selection and implementation of new technologies. A case study will be used demonstrate this decision-making process for the selection of both a new chromatography technology and a new single use filtration technology.
1:45 p.m. – 2:05 p.m. **Managing Raw Material Risks for Biopharmaceuticals and Cell Therapies** **Karen Walker,** Head, Cell and Gene Therapy Quality, *Novartis*	1:45 p.m. – 2:15 p.m. **Multi-Product & Multi-Purpose Patient Facilities** **Harry Lam, PhD,** Vice President, Head of Biologics Manufacturing, *PCT-Caladrius*	1:45 p.m. – 2:15 p.m. **A Case Study for Evaluating New Technologies** **Younok Dumortier Shin,** Director, Global Tech Operations, *Janssen Pharmaceuticals*

MONDAY, MARCH 14, 2016 AGENDA (CONTINUED)

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A1 – Achieving High Quality and Productivity in Cell Culture Processes *(continued)*	**B1 – Ensuring Supply by Using Multiproduct Facilities and Reducing Supply Chain Risk** *(continued)*	**C1 – Integrating New Technologies and Products: Processes and Tools for Managing Decisions and Execution** *(continued)*
2:05 p.m. – 2:25 p.m. **Increases in Productivity by Progressive Cell Culture Medium Optimization** **Tongtong Wang, PhD,** Senior Director, Bioprocess R&D and Operation, *Eli Lilly & Company* 2:25 p.m. – 2:45 p.m. **Advances in Primary Recovery and Cell Retention** **Louis Masi,** Vice President and Founding CEO, *FloDesign Sonics, Inc.* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**	2:15 p.m. – 2:45 p.m. **Supply Chain for Personalized Medicines – Facing the Challenges** **George O'Sullivan,** Senior Director, Supply Chain and Strategic Sourcing, *Kite Pharma* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**	2:15 p.m. – 2:45 p.m. **Application of QRM in Cell Therapy Manufacturing (Needle to Needle)** **Bernadette Keane,** Vice President, QA/QC, *bluebird bio* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**

3:15 p.m. – 4:00 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

4:00 p.m. – 5:15 p.m.
Concurrent Interest Group Sessions

IG1 – Vaccines	**Leader: John Finkbohner, PhD,** Senior Policy Director – US, *AstraZeneca* **Interest Group Description:** The Vaccines Interest Group focuses on issues that affect the biological, biotechnology and vaccine industry. The Interest Group has previously discussed regulatory issues, new technologies and emerging industry trends. Recent issues include vaccine availability and supplies, homeland security and inspection trends. This session will focus on these issues and includes a look at how information shared at the 2015 PDA/FDA Vaccines Conference (Dec 2015) might inform our view of future trends.
IG2 – Biotechnology	**Leader: Vince Anicetti,** Senior Vice President, Quality and Compliance, *Coherus Biosciences* **Interest Group Description:** The interest group will address the following aspects of Biosimilar development: FDA perspective on risk ranking of product quality attributes and their respective tier approach, judging significance of differences, industry perspective on practical considerations in CQA tier selection, assessing quality differences from originator product and impact and differentiating similarity studies and specification/shelf life rationale. Additional areas for discussion include: stability strategies, number of lots needed for similarity assessment, selection of reference materials and when to use comparability vs. similarity standards.
IG3 – Combination Products	**Leader: Lee Leichter,** President, *P/L Biomedical* **Interest Group Description:** The newly re-formed Combination Products IG provides a forum for discussion of topical issues concerning technical, regulatory (submissions) and compliance matters related to combination product types with emphasis on drug delivery devices and functional pharmaceutical packaging.

MONDAY, MARCH 14 – TUESDAY, MARCH 15, 2016 AGENDA

IG4 – Facilities & Engineering	**Leader: Shelley Preslar,** Vice President, Southeast Operations, *Azzur Group* **Interest Group Description:** The Facilities and Engineering Interest Group provides a forum for the discussion of topics and interests related to the design, construction, operation and maintenance of the production and research facilities used for GMP and GLP purposes. The format of this IG's meeting is an open forum for discussion. Together, we discuss hot topics in the industry that apply to Facilities and Engineering across the spectrum of Aging Facilities to New Trends and Technology. By sharing lessons learned and best practices, we aspire to help each other address challenges that we face in our daily operations and spark innovation. We will review survey results regarding the Group's main points of interest, and evaluate the potential for deep dives into any particular technical area related to F&E.
IG5 – Microbiology/ Environmental Monitoring	**Leader: Jeanne Moldenhauer,** Vice President, *Excellent Pharma Consulting* **Interest Group Description:** The IG will have a lively discussion on implementation of USP <1116> and environmental monitoring. Panelists will be giving a brief set of comments followed by group discussion.

5:15 p.m. – 6:45 p.m.
Networking Reception in Exhibit Hall

TUESDAY, MARCH 15, 2016

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

7:15 a.m. – 8:30 a.m.
Continental Breakfast

7:15 a.m. – 8:15 a.m.
Concurrent Breakfast Sessions

Breakfast I: The Flexible and Agile Facility of the Future **Moderator: Maik Jornitz,** President, *G-Con Manufacturing, Inc.*	**Breakfast II: QRM in Engineering Design** **Moderator: Susan Schniepp,** Consultant, *Regulatory Compliance Associates, Inc.*	**Breakfast III: QbD-Enabled Control Strategies/Process Validation of Biosimilar Processes** **Moderator: Steven Lynn,** Global Head Group Compliance and Audit, *Novartis*	**Breakfast IV: Serialization** **Moderator: Véronique Davoust, PharmD,** Manager, Global Quality Strategy, *Pfizer, Inc.*
Session Description: A major financial burden is capital expenses invested into rigid production facilities, which are often only designed to facilitate one product, are very inflexible in regard to scaling-up and down and are unable to be divested if the drug target fails or the product patent expires. The predicament of investment versus financial risk mitigation was a major problem for start-up companies, but nowadays affect as much large biopharma. Furthermore, the	**Session Description:** Aging products offer a unique challenge when companies chose to upgrade their facilities and processes to meet today's standards. This could compromise a company's ability to provide necessary medicine to patients. This session will focus on applying QMR and modern engineering concepts to older products to bring them up to today's standards.	**Session Description:** The emergence of biosimilar products in the industry has raised a number of questions about how these products are validated and determined to be equivalent to the original product. This session will try and answer how QbD control strategies are employed when validating manufacturing processes for biosimilar products. The expert speakers will provide information based on their experience with biosimilar products and the challenges of providing	**Session Description:** This session aims to aid in clarifying expectations for serialization and its practical implementation from an industry perspective. After a brief overview of the international global environment, a featured speaker will inform about the U.S. DSCSA requirements and focus on the implementation efforts to date, lessons learned and next steps.

TUESDAY, MARCH 15, 2016 AGENDA (CONTINUED)

Breakfast I: The Flexible and Agile Facility of the Future *(continued)*	**Breakfast II:** QRM in Engineering Design *(continued)*	**Breakfast III:** QbD-Enabled Control Strategies/Process Validation of Biosimilar Processes *(continued)*	**Breakfast IV:** Serialization *(continued)*
multi-patient treatments to low volume individual patient treatment. Production site design flexibility is becoming a key element, so much that plug and play options are required. This session will review current and upcoming facility models, which create flexibility, reduced time-to-run and investment.		relevant validation information demonstrating the suitability of biosimilars for the pharmaceutical industry.	
7:15 a.m. – 7:45 a.m. **Morten Munk,** Senior Technology Partner, *NNE Pharmaplan* 7:45 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:45 a.m. **Jason Martin,** Director, External Supply Quality Operations, Americas, *Novartis-Sandoz, Inc.* 7:45 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:35 a.m. **Vince Anicetti,** Senior Vice President, Quality, *Coherus Biosciences* 7:35 a.m. – 7:55 a.m. **Susanne Richter, PhD,** Head DSP Development Cell Culture, *Sandoz GmbH* 7:55 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:45 a.m. **Peggy Staver,** Director, Product Integrity, *Pfizer, Inc.* 7:45 a.m. – 8:15 a.m. **Questions and Answers/Discussion**

8:30 a.m. – 10:00 a.m.
P3 – Improving Efficiency and Reducing Manufacturing Cost
Moderator: Glenn Wright, Senior Director, Project Management, Technical Services/Manufacturing Science, *Eli Lilly & Company*

Session Description: What was once a futuristic vision is becoming reality as manufacturers work to develop and implement manufacturing processes that incorporate continuous manufacturing to provide greater production efficiency as well as single use systems to maximize product flexibility and reduce the overall manufacturing footprint. Join us as we take a deeper look at both of these approaches and how they are being applied to meet the needs of our industry and the patients we serve.

8:30 a.m. – 9:00 a.m.
Single Use Systems: Manufacturing of the Future
Kimball Hall, Vice President, Manufacting, *Amgen, Inc.*

9:00 a.m. – 9:30 a.m.
Continuous Manufacturing
Konstantin Konstantinov, Vice President, Technology Development, *Genzyme*

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

9:45 a.m. – 4:00 p.m.
Exhibit Hall Open

TUESDAY, MARCH 15, 2016 AGENDA (CONTINUED)

10:00 a.m. – 10:45 a.m.
Refreshment Break, Poster Presentations and Passport Raffle Drawing in the Exhibit Hall

10:45 a.m. – 12:15 p.m.
Concurrent Sessions

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A2 – Challenges and Advances within Downstream Technologies **Moderator: Morten Munk,** Senior Technology Partner, *NNE Pharmaplan*	**B2 – Adapting Manufacturing Facilities – Case Studies** **Moderator: Ghada Haddad,** Director, Engineering, Sterile & Validation, *Merck & Company, Inc.*	**C2 – Driving Continuous Process Improvement through Effective Lifecycle Management** **Moderator: Susan Schniepp,** Consultant, *Regulatory Compliance Associates, Inc.*
Session Description: For a long period of time, the biopharmaceutical industry focus has been on optimizing and improving the upstream process steps, which to a large extent has been accomplished. This has led to increased attention on the downstream process area to ensure this part of the process does not become a bottleneck for an increased productivity and cost-effectiveness in biopharmaceutical manufacturing. Disruptive innovation is required to meet the demand for cost-effective and especially flexible purification solutions, which meets the same level of improvements as seen, for example, in the cell culture area. This session will address some of the challenges this historically conservative industry is facing, and give insight to the opportunities for innovation within existing technologies as well as discuss the possibilities for introduction of new technologies in the downstream area. Even continuous manufacturing cannot be described as a novel concept in industrial manufacturing; its use is still quite scarce in the downstream area. However, over the last few years the interest has increased dramatically and an increasing number of suppliers are now offering attractive technical solutions that also meet quality and regulatory requirements. This development might have been supported by the positive experience of the advantages of the implementation of Single Use Technologies (SUT) in several are areas of	**Session Description**: Do you have an aging facility? Sometimes it can seem that our facilities are out of date by the time the first product is manufactured. In this session, two case studies will be shared to address the challenges with aging facilities. The first case study will discuss a facility that is a dependable and reliable quality manufacturing site, but has fallen behind the technology curve. An additional factor includes addressing containment of hazardous compounds. As part of continuous improvement, the process of determining which technologies are appropriate for incorporation into the facility will be evaluated. The second case study will discuss an organization with compliance risks associated with an aging facility, with an added concern about the potential for drug shortages and customer service. The case study will evaluate how to maintain quality production while mitigating the compliance risks.	**Session Description:** Implementing new procedures and processes at a manufacturing facility takes time and resources. This session will present practical solutions for using analytical control systems and product and process monitoring information that will help successfully drive continuous improvement at your facility. The case studies are real-life examples from leading pharmaceutical companies that will educate the participants on how continuous improvement can be achieved and successfully implemented.

TUESDAY, MARCH 15, 2016 AGENDA (CONTINUED)

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A2 – Challenges and Advances within Downstream Technologies *(continued)*	**B2 – Adapting Manufacturing Facilities – Case Studies** *(continued)*	**C2 – Driving Continuous Process Improvement through Effective Lifecycle Management** *(continued)*
downstream processing. One example of an area within SUT that has developed over the last years is pre-packed chromatographic columns. But in order for this area to develop even further, the impact on the total production costs has to be addressed. The combination of pre-packed columns and continuous chromatography might be the solution that can get those two technologies more widely accepted and implemented in the industry.		
10:45 a.m. – 11:15 a.m. **Host Cell Proteins** **Gunter Jagschies, PhD,** Senior Director, Strategic Customer Relations, *GE Healthcare Life Sciences* 11:15 a.m. – 11:45 a.m. **Downstream Process Monitoring and PAT for Implementation of Continuous Bioprocessing** **Veena Warikoo,** Director, Purification Development, *Genzyme – A Sanofi Company* 11:45 a.m. – 12:15 p.m. **Questions and Answers/Discussion**	10:45 a.m. – 11:15 a.m. **Case Study – A Single Use System as an Enabler for Converting a Dedicated, Cytotoxic, Parenteral IMP Facility to Multi-Purpose IMP Manufacturing** **Tsutomu Ota,** Manager, Global IMP GMP Assurance, *Takeda Pharmaceutical Company Ltd.* 11:15 a.m. – 11:45 a.m. **Implementing Changes to a Facility While it Continues to Operate** **George Wiker,** Executive Director, *AES Clean Technology, Inc.* 11:45 a.m. – 12:15 p.m. **Questions and Answers/Discussion**	10:45 a.m. – 11:15 a.m. **Lifecycle Management of Analytical Control System – A Practical Application Case Study** **Paul Motchnik,** Associate Director, Analytical Control System Lifecycle Management, *Genentech, a Member of the Roche Group.* 11:15 a.m. – 11:45 a.m. **Case Study – Leveraging Product and Process Monitoring to Drive Continual Improvement** **Dan Blackwood,** Associate Research Fellow, *Pfizer, Inc.* 11:45 a.m. – 12:15 p.m. **Questions and Answers/Discussion**

12:15 p.m. – 1:45 p.m.
Lunch on Your Own. Exhibit Hall Closed – *A listing of local restaurants is available at the PDA Registration Desk*

The PDA Annual Meeting absolutely stands apart from other conferences for its intent focus on premium scientific, technical and regulatory programming. The program and exhibition provide us access to the top thought leaders in the industry! Thank you!

– STACIE BYARS, *CMC Biologics*

TUESDAY, MARCH 15, 2016 AGENDA (CONTINUED)

1:45 p.m. – 3:15 p.m.
Concurrent Sessions

Advances in Bioprocess Development	Innovation in Manufacturing Sciences	Lifecycle Management and Continuous Improvement
A3 – Advances in Analytical Technologies for Microbial Control **Moderator: Emabelle Ramnarine,** Senior Director, Head Global Biologics Quality Control, *Genentech, a Member of the Roche Group*	**B3 – Review of Single-Use Processing Equipment Experiences and Needs** **Moderator: Maik Jornitz,** President, *G-Con Manufacturing, Inc.*	**C3 – From Development to Commercialization – Technical Transfer Strategies and the Use of Development Data in Validation Plans** **Moderator: Glenn Wright,** Senior Director, Project Management, Technical Services/Manufacturing Science, *Eli Lilly & Company*
Session Description: There are continued advances in microbial and adventitious agents control strategies and detection technologies across the industry for biologics manufacturing. This session will share advances and practical application considerations on two hot analytical technology topics for biopharmaceuticals – PCR-based testing of microbial contaminants and endotoxin masking/demasking phenomenon in different biological product matrices.	**Session Description:** Single-use process technologies are not new any longer, but well established within the industry. The session will reflect back on the experiences with single-use technologies, the benefits and obstacles, how these technologies are implemented and used. It will also review technology improvement needs, for example, robust integrity test strategies for some of the bags and bioreactors utilized.	**Session Description:** This session will discuss tech transfer strategies developed as products move from development to commercial manufacturing as well as the use of development data in validation plans and through the process lifecycle.
1:45 p.m. – 2:15 p.m. **Masking and Demasking of Endotoxins in Common Biological Product Matrices** **Johannes Reich,** PhD Student, *University of Regensburg/Hyglos GmbH* 2:15 p.m. – 2:45 p.m. **Advances in Adventitious Agents Control Strategies** **Sven Deutschmann,** Director, Microbiology & Cell Biology, Global MMTech Head PCR & Nucleic Acid Technologies, *Roche Diagnostics GmbH* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**	1:45 p.m. – 2:15 p.m. **Single Use Technology – Experience from Large-Scale Commercial SUS Facilities** **Chris Chen, PhD,** Senior Vice President & Chief Technology Officer, *WuXi AppTec* 2:15 p.m. – 2:45 p.m. **Integrity Testing of Single Use Bags and Bioreactors** **Marc Hogreve,** Senior Scientist for Integrity Testing Solutions, *Sartorius Stedim Biotech GmbH* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**	1:45 p.m. – 2:15 p.m. **Commercial Tech Transfer Strategies for New Products** **David Allen, PhD,** Senior Director, Parenteral TS/MS, *Eli Lilly & Company* 2:15 p.m. – 2:45 p.m. **Continuous Use of Development Data in Validation Plans and the Process Lifecycle** **Scott Bozzone**, Senior Manager, Quality Systems & Compliance Validation, *Pfizer, Inc.* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**

3:15 p.m. – 4:00 p.m.
Refreshment Break, Poster Presentations and Passport Raffle Drawing in the Exhibit Hall

TUESDAY, MARCH 15, 2016 AGENDA (CONTINUED)

4:00 p.m. – 5:15 p.m.

Concurrent Interest Group Sessions

IG6 – Pharmacopeial/ Management of Outsourced Operations	**Leaders: Janeen Skutnik-Wilkinson,** Corporate Quality, *Biogen Idec, Inc.*, and **Susan Schniepp,** Consultant, *Regulatory Compliance Associates, Inc.* **Interest Group Description:** The Outsourcing and Pharmacopeial IGs will meet jointly at the 2016 PDA Annual Meeting. The discussion will focus on the results of the recent PDA Pharmacopeial Survey to determine the best way PDA can assist the membership in understanding and commenting on Pharmacopeial Initiatives.
IG7 – Process Validation	**Leaders: Scott Bozzone,** Senior Manager, Quality Systems & Compliance Validation, *Pfizer, Inc.*, and **Vijay Chiruvolu, PhD,** Senior Director, Product Sciences, *Kite Pharma* **Interest Group Description:** This IG will focus on opportunities and challenges in the process validation area. We will share and discuss the lessons learned from implementing the lifecycle process validation approach, including any regulatory responses or inspection experiences. In addition, there will be a presentation on process validation approaches for biosimilars and cell/gene therapy products. Finally, there will be time for open discussion to share and benchmark on best industry practices.
IG8 – Quality Risk Management	**Leaders: Jeff Hartman**, Senior Consultant, *Concordia ValSource, LLC*, and **Emabelle Ramnarine,** Senior Director, Head Global Biologics Quality Control, *Genentech, a Member of the Roche Group* **Interest Group Description:** The RAQAB balloted and approved (4 August 2015) a research collaboration between PDA and Dublin Institute of Technology's (DIT) Pharmaceutical Regulatory Science Team. The research was led by Kelly Waldron, PhD, Researcher in Quality Risk Management (QRM) at DIT and Manager of Quality Risk Management at *Genzyme*. The QRM Interest Group, through PDA Connect℠, has been actively engaged with Kelly on this project. Kelly would like to share some of her research findings with the group during this session. Data and discussions will include: • Review of the QRM Benchmarking survey results • Analysis of results with regard to industry's perceived level of QRM maturity and realized value from QRM activities • Conclusions regarding implications of the research: what does it mean for industry? What are the next steps with regard to additional research?
IG 9 – Sterile Processing	**Leader: Edward Tidswell, PhD,** Senior Director, Sterility Assurance, *Baxter Healthcare Corporation* **Interest Group Description:** The manufacture of sterile products requires robust process and environmental controls (including layers of redundancy) to assure suitable assurance of sterility. This IG session will review past, current and future (known and likely) guidance and regulations to achieve and sustain the sterility assurance of drug and device products.
IG10 – Supply Chain Management	**Leader: Lucy Cabral,** Head of Global Supplier Quality & Product Validity, *Genentech, a Member of the Roche Group* **Interest Group Description:** The Supply Chain Management IG 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 IG discusses current industry topics and shares best industry practices to meet quality and business requirements by partnering and collaborating with suppliers around the world.

TUESDAY, MARCH 15 – WEDNESDAY, MARCH 16, 2016 AGENDA

IG11 – Visual Inspection of Parenterals	**Leader: John Shabushnig, PhD,** Principal Consultant, *Insight Pharma Consulting, LLC* **Interest Group Description:** The Visual Inspection of Parenterals IG provides a forum to discuss topics related to the visual inspection of injectable products. A review of recent FDA 483 observations, warning letters and recalls will be presented. We will also discuss the new USP Chapter <790> *Visible Particulates in Injectables* and the associated Information Chapter <1790> *Visual Inspection of Injectables*. We will plan time to discuss topics of interest and recent experiences of those in attendance. Past topics have included selection and qualification of human inspectors, validation of automated inspection systems, inspection of protein-based biopharmaceuticals, inspection of other difficult products or packages and country specific inspection requirements.

6:00 p.m. – 8:00 p.m.
70th Anniversary Gala Event

WEDNESDAY, MARCH 16, 2016

7:00 a.m. – 12:00 p.m.
Registration Open

7:00 a.m. – 8:30 a.m.
Continental Breakfast

7:15 a.m. – 8:15 a.m.
Concurrent Breakfast Sessions

Breakfast V: Data Integrity **Moderator: Susan Schniepp,** Consultant, *Regulatory Compliance Associates, Inc.*	**Breakfast VI: Manufacturing Initiative** **Moderator: William Miele, PhD,** Director/Team Leader, Microbiology & Aseptic Support, *Pfizer, Inc.*	**Breakfast VII:** Defining the Product Specification **Moderator**: **Michael DeFelippis**, **PhD**, Senior Research Fellow, *Eli Lilly & Company*	**Breakfast VIII:** Post-Approval Life-Cycle Management Plans/Change Management **Moderator**: **Kerry Ingalls,** Vice President, Regional Manufacturing, *Amgen Ireland*
Session Description: Data integrity has become a major concern for the industry and regulators. This session will focus on some recent data integrity issues and explain the reason they are a problem, what you can do to remediate them and how to prevent them from recurring. In addition, the leader of the PDA task force on data integrity will give an update on how PDA is addressing this issue on behalf of its members.	**Session Description:** The PDA Manufacturing Initiative (officially titled the "PDA Manufacturing Science Program [MSP℠]") is now underway. As we think of pharmaceutical manufacturing's future – what will it require – what areas do we as an industry need to be focusing on in regards to our manufacturing operations (the technology, the process, the people)? This session will discuss the new initiative and how PDA is assuring a clear focus on manufacturing's future and its success.	**Session Description:** The strategy for defining specifications for biopharmaceutical drug substances and drug products follows an iterative process. Early versions of the specifications typically include wider acceptance criteria for most tests because material used in Phase 1 and 2 clinical trials is often derived from immature processes, there is limited manufacturing experience, very few batches are produced and the final	**Session Description:** Products that have been released on the market change over time and must be monitored as they transition through stages. A robust change control system should be put in place to monitor changes affecting the product and ensure they are compliant with regulatory guidelines. This session will address challenges and strategies from a regulatory perspective when assessing and reporting changes associated with product life-cycle management. analytical testing strategy is likely not defined. Regulatory authorities are aware of these considerations and generally

WEDNESDAY, MARCH 16, 2016 AGENDA (CONTINUED)

Breakfast V: Data Integrity *(continued)*	**Breakfast VI:** Manufacturing Initiative *(continued)*	**Breakfast VII:** Defining the Product Specification *(continued)*	**Breakfast VIII:** Post-Approval Life-Cycle Management Plans/Change Management *(continued)*
		allow greater flexibility in the initial stages of clinical investigation, but also expect that sponsors will evolve the specifications to incorporate tighter acceptance criteria during Phase 3 and certainly by the time the product is submitted for licensure. ICH Q6B states that the specifications should be linked to preclinical and clinical studies, the manufacturing process, analytical procedures and account for drug substance and drug product stability. However, regulators often base allowable acceptance criteria primarily on material that was used in pivotal clinical studies. Because these batches are not representative of long-term process variability, it may be difficult to achieve adequate manufacturing capability for all specification tests. This session will explore the process for defining biopharmaceutical product specifications and discuss approaches for meeting regulator expectations while simultaneously ensuring robust manufacturing capability.	
7:15 a.m. – 7:45 a.m. **Andrew Harrison,** Chief Regulatory Affairs Officer and General Counsel, *Regulatory Compliance Associates, Inc.* 7:45 a.m. – 8:00 a.m. **Anil Sawant, PhD,** Vice President, Quality Management Systems, *Merck Sharp and Dohme Corporation* 8:00 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:45 a.m. **Glenn Wright,** Senior Director, Project Management, Technical Services/ Manufacturing Science, *Eli Lilly & Company* 7:45 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:45 a.m. **Ciaran Brady, PhD,** Director, Biotech Technical Services/ Manufacturing Sciences, *Eli Lilly SA* 7:45 a.m. – 8:15 a.m. **Questions and Answers/Discussion**	7:15 a.m. – 7:35 a.m. **Mahesh Ramahandran,** Branch Chief (Acting), Office of Manufacturing & Product Quality, CDER, *FDA* 7:35 a.m. – 7:55 a.m. **Walter Kalmans,** President, *Lontra Ventures, LLC* 7:55 a.m. – 8:15 a.m. **Questions and Answers/Discussion**

WEDNESDAY, MARCH 16, 2016 AGENDA (CONTINUED)

8:30 a.m. – 10:00 a.m.
P4 – Rapid Product Development
Moderator: Emabelle Ramnarine, Senior Director, Head Global Biologics Quality Control, *Genentech, a Member of the Roche Group*

Session Description: Accelerated regulatory approvals are invaluable for expediting availability of medically necessary products to patients. However the accelerated timelines associated with such submissions can present companies with many challenges from a product development and CMC standpoint, because the ultimate objective of ensuring that patients are provided with safe, efficacious, quality products cannot be compromised on account of the accelerated timelines. Presenters in this session will discuss considerations for rapid product development from CMC and regulatory points of view, for products with expedited approval designations.

8:30 a.m. – 9:00 a.m.
CMC Considerations When a Drug Development Project is Assigned Breakthrough Therapy Status
Earl Dye, PhD, Director, Technical Regulatory Policy, *Genentech, a Member of the Roche Group*

9:00 a.m. – 9:30 a.m.
Case Study – Breakthrough Designation
FDA Presenter Invited

9:30 p.m. – 10:00 a.m.
Questions and Answers/Discussion

10:00 a.m. – 10:30 a.m.
Refreshment Break

10:30 a.m. – 12:00 p.m.
P5 – Ensuring Supply of Medicines and Expanding Access
Moderator: Michael DeFelippis, PhD, Senior Research Fellow, *Eli Lilly & Company*

Session Description: Ensuring an uninterrupted supply of medicine is a primary focus of the pharmaceutical industry. Mitigating risk of drug shortages requires investment in manufacturing facilities and other continuous improvement initiatives throughout the product lifecycle. However, ensuring that patients throughout the world have access to high-quality and affordable pharmaceutical products, particularly in developing countries and emerging markets, has many challenges and requires additional manufacturing and logistical considerations. Healthcare crises, such as the recent Ebola epidemic, represent another challenge to traditional development and manufacturing models and alternative strategies are required to enable expedited availability of novel therapies to the marketplace when they are critically needed. These issues will be addressed in this plenary session with presentations focused on rapid commercialization of Ebola vaccines and strategies for expanding access in emerging markets.

10:30 a.m. – 11:00 a.m.
Development, Manufacturing and Supply of Ebola Vaccines
Jeffrey Blue, Director of Vaccine Drug Product Development, *Merck & Company, Inc.*

11:00 a.m. – 11:30 a.m.
Expanding Access in Emerging Markets
Jayanth Sridhar, PhD, Global Head of Biologicals Manufacturing, *Cipla Limited*

11:30 a.m. – 12:00 p.m.
Questions and Answers/Discussion

12:00 p.m.
Closing Remarks and Adjournment
Michael DeFelippis, PhD, Senior Research Fellow, *Eli Lilly & Company,* and Co-Chair, *2016 PDA Annual Meeting* Program Planning Committee

NETWORKING AND OTHER AREA ACTIVITIES

SUNDAY, MARCH 13, 2016

7:00 a.m. – 10:00 a.m.

10th Annual Walk/Run Event *(Optional Event)*

Benefiting the Fisher House

On your mark, Get set, Go...to the PDA 10th Annual Walk/Run Event. Set off on your choice of a 5k run or 3k walk through the outdoors of San Antonio. Start your week with a fresh breeze and light workout with colleagues, family and friends. There will be prizes for the first, second and third place winners of the walk and run and a good time for all.

FISHER HOUSE – Wilford Hall Fisher House is a home-away-from-home for the families of seriously ill or injured patients receiving treatment at Wilford Hall Ambulatory Surgical Center, San Antonio Military Medical Center or other medical facilities in the San Antonio Area at no cost.

$45.00 per person. *All proceeds go to Fisher House.*

7:00 a.m. – 12:00 p.m.

PDA Golf Tournament

(TPC San Antonio Golf Course)

TPC San Antonio opened in 2010 with 36 holes of golf designed by two of golf's most respected and innovative architects and World Golf Hall of Fame members, Pete Dye and Greg Norman. TPC San Antonio's magnificent pair of championship golf courses offers epic golf in a pristine natural setting. While very different from the traditional, tree-lined AT&T Oaks Course, the AT&T Canyons Course will stand on its own as a tournament venue in terms of design, strategy and beauty. This course sits on a great piece of land which provides panoramic views of an adjacent 700 acre nature preserve. The design, which measures more than 7,100 yards, is true to nature and the flow of the land. The dramatic elevation changes and hill country views make this course not only challenging, but breathtaking as well.

$250.00 per person. *Includes tee time, bag valet, cart, range of balls, tournament management and lunch. Club and shoe rentals are available at an additional expense.*

MONDAY, MARCH 14, 2016

5:15 p.m. – 6:45 p.m.

Networking Reception in Exhibit Hall

Relax and unwind at the end of day one by attending the networking reception in the Exhibit Area. This is you first chance to find new suppliers and service providers and to discuss the day's sessions and hot topics with colleagues in an informal atmosphere.

TUESDAY, MARCH 15, 2016

6:00 p.m. – 8:00 p.m.

70th Anniversary Gala Event

Other Area Activities:

Lantana Spa Treatments

Looking to get pampered? The Lantana Spa at The JW Marriott San Antonio Hill Country offers a number of spa services for all of your rejuvenation needs.

Spa hours: 7:00 a.m. – 8:00 p.m.
(Appointments begin at 8:00 a.m.)

To ensure availability, please book in advance by calling +1 (210) 276-2300

Booking Code: PDA *(Advanced booking of 2 weeks is required online)*

PDA 2016 Annual Meeting attendees will receive a 15% discount on the following service categories:

- Massage Therapy
- Body Treatments
- Facial Skincare
- Nail Care
- Enhancements
- Lantana Spa Retail Shop

** Spa packages or already discounted treatments are not included in the discounted rate **
Cancellation Policy: 24 hour notice of cancellation is required

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

PREPARING FOR THE NEXT GENERATION OF REGULATORY INSPECTIONS: A 2016 PDA MANUFACTURING SCIENCE WORKSHOP

March 16-17, 2016

JW Marriott San Antonio Hill Country Resort & Spa | San Antonio, TX

Program Planning Committee

Program Chairs:

Véronique Davoust, PharmD
Pfizer, Inc.

Susan Schniepp
Regulatory Compliance Associates

Maik Jornitz
G-Con Manufacturing, Inc.

Emabelle Ramnarine
Genentech, a Member of the Roche Group

Glenn Wright
Eli Lilly & Company

Wanda Neal
PDA

A Message from the Chairs

Véronique Davoust, PharmD
Pfizer, Inc.

Susan Schniepp
Regulatory Compliance Associates, Inc.

Dear Colleagues,

The Parenteral Drug Association will host the 2016 PDA Manufacturing Science Workshop on March 16-17at the JW Marriott in San Antonio immediately following the 2016 Annual Meeting. Titled *Preparing for the Next Generation of Regulatory Inspections,* the workshop will concentrate on critical issues such as data integrity, manufacturing controls and variability for older products, and how to use historical information and apply this knowledge during inspections.

The Opening Plenary session will introduce the key issues with presentations such as *Inspecting for Data Integrity: From Manufacturing Floor to Quality Control Laboratories* and *Understanding Process Variability as an Inspection Tool*.

The plenary will set the stage for the subsequent breakout sessions where all participants will become active participants in focused discussions that will cover a range of concepts from *Calculating the Business Case for Process Improvement* to *Approaches for Incorporating Process Variability Tools to Identify Areas for Improvement*. Furthermore, participants will learn how to establish a continuous improvement cycle for analytical methods and the impact it can have on manufacturing controls. Industry leaders who are actively involved in PDA's Aging Facilities taskforce will lead these discussions.

Workshop participants will also be given an opportunity to role-play in a Fishbowl session discussing what is holding the industry back from improving our processes and methods in order to assure we deliver quality products to patients.

The workshop will conclude with a Closing Plenary that will offer attendees advice on using continuous manufacturing control strategies to manage process variability. Participants will be able to extract and apply this guidance at their own organizations to optimize existing products and processes so they are prepared for their next inspection.

We hope you are as excited as we are about the Workshop and encourage you to join us in engaging in open and honest discussion on this timely subject.

Sincerely,

Sue Schniepp and Véronique Devoust

PREPARING FOR THE NEXT GENERATION OF REGULATORY INSPECTIONS: A 2016 PDA MANUFACTURING SCIENCE WORKSHOP (CONTINUED)

Preparing for the Next Generation of Regulatory Inspections: A 2016 PDA Manufacturing Science Workshop
CPE: ACPE # 0116-0000-15-017-L04-P | 0.9 CEUs
Type of Activity: *Knowledge*

Learning Objectives

Upon completion of this workshop, participants will be able to:

- Explain the changes in regulatory philosophy toward older products and how these changes may impact investigations
- Describe data integrity issues associated with process variability and how to prevent them
- Summarize the barriers and the challenges in updating product portfolios to meet today's expectations
- Discuss improvements to pharmaceutical manufacturing for API/biopharmaceutical drug substance as well as finished products
- Discuss barriers to modernize and continually improve facilities, processes or analytics and methodology development due to difficulties in post approval change requirements
- Explain human error and ways to prevent it as it relates to the manufacturing process
- Identify effective ways to review modernization needs, develop action plans and implement change

Who Should Attend

Personnel from CMC | Regulatory | Inspection Management | Auditors | Manufacturing | Operations | Technical Services | Validation | QA/QC | Quality and Operations Management

Departments: Manufacturing | Quality | Research & Development | Regulatory Affairs | Engineering | Laboratory Science | Information Technology | Validation | Training

WORKSHOP AGENDA

WEDNESDAY, MARCH 16, 2016

12:00 p.m. – 5:00 p.m.
Registration Open

1:00 p.m. – 1:10 p.m.
Welcome and Opening Remarks
Véronique Davoust, PharmD, Senior Manager, Global Quality Intelligence, *Pfizer, Inc.*, and Co-Chair, *2016 Manufacturing Science Workshop* Program Planning Committee

1:10 p.m. – 2:40 p.m.
P1 – Understanding the New Regulatory Inspections Models: Data Integrity and Manufacturing Controls and Variability
Moderator: Véronique Davoust, PharmD, Senior Manager, Global Quality Intelligence, *Pfizer, Inc.*

Session Description: Over the last few years, an increased focus on data integrity has been observed through inspections worldwide. Representatives from regulatory authorities and industry will start the conference with a look at the new expectations of inspectors in terms of data integrity, and how the manufacturing control strategies put in place to manage process variability can effectively meet and be used as an efficient internal and external inspections tool for the ultimate benefit of the patients.

2:40 p.m. – 3:00 p.m.
Refreshment Break

3:00 p.m. – 5:00 p.m.
Working Group Sessions

3:00 p.m. – 4:00 p.m.
Work Session 1 – Understanding Process Variability and Identifying Areas for Process Improvement
Moderator: Glenn Wright, Senior Director, Project Management, Manufacturing Science and Technology, *Eli Lilly & Company*

4:00 p.m. – 5:00 p.m.
Work Session 2 – Approaches for Incorporating Process Variability Tools to Identify Areas for Improvement
Moderator: Harold Baseman, Chief Operating Officer, *ValSource, LLC*, and Chair, *PDA*

5:00 p.m. – 6:15 p.m.
Networking Reception in Exhibit Hall

PREPARING FOR THE NEXT GENERATION OF REGULATORY INSPECTIONS: A 2016 PDA MANUFACTURING SCIENCE WORKSHOP (CONTINUED)

THURSDAY, MARCH 17, 2016

7:30 a.m. – 5:00 p.m.
Registration Open

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

8:30 a.m. – 10:30 a.m.
Working Group Sessions

8:30 a.m. – 9:30 a.m.
Work Session 3 – Human Error and Quality Culture
Moderator: Emma Ramnarine, Senior Director and Head, Global Quality Risk Management, *Genentech, a Member of the Roche Group*

Session Description: The working group sessions will provide the opportunity for participants to discuss problems associated with the related topic.

9:30 a.m. – 10:30 a.m.
Work Session 4 – Preventing Data Integrity Issues
Moderator: Anil D. Sawant, PhD, Vice President, Quality Management Systems and External Affairs, *Merck Sharp and Dohme Corporation*

Session Description: The working group sessions will provide the opportunity for participants to discuss problems associated with the related topic.

10:30 a.m. – 11:00 a.m.
Refreshment Break

11:00 a.m. – 12:00 p.m.
Work Session 5 – Continuous Improvement Cycle for Analytical Methods and its Impact to Manufacturing Controls
Moderator: Marsha Stabler-Hardiman, Senior Consultant, *ValSource, LLC*

12:00 p.m. – 1:30 p.m.
Lunch

1:30 p.m. – 2:30 p.m.
Fishbowl Discussion

1:30 p.m. – 2:30 p.m.
Fishbowl – What's Holding Us Back from Improving Our Processes and Methods?
Moderator: Susan Schniepp, Consultant, *Regulatory Compliance Associates, Inc.*

Session Description: The Fishbowl discussions will provide valuable insight into the most appropriate way to improve processes and methods. This will be a very interactive, serious yet entertaining session.

2:30 p.m. – 3:00 p.m.
Refreshment Break

3:00 p.m. – 4:30 p.m.
P2 – Using Continuous Manufacturing Control Strategies to Manage Process Variability
Moderator: Maik Jornitz, President, *G-Con Manufacturing, Inc.*

Session Description: Continuous manufacturing is becoming a popular manufacturing modus in oral solid dosage forms and bioprocessing. Major continuous processing efficiencies have been reported, but new processing technologies and control strategies are required to assure consistent and repeatable product composition and quality. Innovative process analytical technologies are implemented into continuous process streams, which allow rapid reaction, if the process stream varies. This track will discuss such new technologies and the capabilities of currently used process control systems.

5:00 p.m.
Workshop Summary and Closing Remarks
Susan Schniepp, Consultant, *Regulatory Compliance Associates, Inc.*, and Co-Chair, *2016 Manufacturing Science Workshop* Program Planning Committee

2016 PDA Conferences and Workshops

PDA Parenteral Drug Association

DATES	EVENT	LOCATION
FEBRUARY 23-24	**Pharmaceutical Microbiology Conference**	Berlin, Germany
MARCH 14-16	**2016 PDA Annual Meeting**	San Antonio, TX
MARCH 16-17	**Preparing for the Next Generation of Regulatory Inspections: A 2016 PDA Manufacturing Science Workshop**	San Antonio, TX
APRIL 12-13	**Parenteral Packaging Conference**	Venice, Italy
APRIL 19-20	**Annex 1 Conference**	San Diego, CA
MAY 17-18	**Visual Inspection Interest Group Workshop**	Bethesda, MD
JUNE 20-21	**Biosimilars Conference**	Chicago, IL
JUNE 27	**Annex 1 Conference**	Berlin, Germany
JUNE 28-29	**Inaugural PDA Europe Annual Meeting**	Berlin, Germany
SEPTEMBER 12-14	**25th Annual PDA/FDA Joint Regulatory Conference**	Washington, DC
SEPTEMBER 14-15	**Data Integrity Workshop**	Washington, DC
SEPTEMBER 20-21	**9th Annual Workshop on Monoclonal Antibodies**	Rome, Italy
SEPTEMBER 27-28	**Pharmaceutical Freeze Drying Technology**	Strasbourg, France
OCTOBER 11-12	**Pharmaceutical Cold & Supply Chain Logistics**	Amsterdam, The Netherlands
OCTOBER 17-18	**PDA Universe of Pre-filled Syringes and Injection Devices**	Huntington Beach, CA
OCTOBER 19	**Drug Delivery/Combination Products Workshop**	Huntington Beach, CA
OCTOBER 24-26	**11th Annual Global Conference on Pharmaceutical Microbiology**	Arlington, VA
OCTOBER 25-26	**Visual Inspection Forum**	Berlin, Germany
OCTOBER 26-27	**Annex 1 Conference**	Washington, DC
NOVEMBER 3-4	**Outsourcing/CMO Conference**	Washington, DC
NOVEMBER 15-16	**Outsourcing & Contract Manufacturing**	Copenhagen, Denmark
DECEMBER 7-8	**Data Integrity Workshop**	San Diego, CA

Subject to change | **pda.org/calendar**

CURRENT AS OF 10/30/2015

PDA Parenteral Drug Association

Connecting People, Science and Regulation®

PDA EDUCATION COURSES

On Thursday and Friday immediately following the *2016 PDA Annual Meeting*, PDA will host six educational courses designed to complement what you learned at the conference. All courses will be held March 17-18, 2016 at the JW Marriott San Antonio Hill Country Resort & Spa.

Continuing Education

Continuing Education for Pharmacists

ACPE®

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits. To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

Continuing Education for Professional Engineers

PDA is an approved provider by the New Jersey State Board of Professional Engineers and Land Surveyors to offer courses to New Jersey Professional Engineers for Continuing Professional Competency (CPC) credit. Following the full participation in this course, participants will receive a Certificate of Accomplishment specifying the number of CPC credits that may be awarded. This certificate can be submitted as verification of completion to the Board for license renewal.

PDA is recognized by the North Carolina Board of Examiners for Engineers and Surveyors as an Approved Sponsor of Continuing Professional Competency (CPC) activities for Professional Engineers licensed by North Carolina. To receive a Certificate of Accomplishment specifying the number of Professional Development Hours (PDHs) that may be awarded, course participants must request the North Carolina Board of Examiners evaluation form from PDA staff. This form must be completed onsite at the conclusion of the course and returned to PDA staff.

Contact Stephanie Ko via email at ko@pda.org to learn more.

For course CEUs and ACPE information for individual courses, see pages 23-25.

Class Schedule

All lecture courses begin at 8:30 a.m. and end at 4:00 p.m. Please arrive at your course location approximately 30 minutes before the start of the course to register and receive your name badge. Please be sure to bring your confirmation letter as proof of registration during check in. PDA will not allow persons to attend a course without payment, or guarantee of payment.

Continental breakfast will be served before class beginning at 7:30 a.m. Lunch will be provided from 12:00 p.m. – 1:00 p.m. Snacks will be provided during the morning break from 10:00 a.m. – 10:15 a.m. and the afternoon break from 2:30 p.m. – 2:45 p.m.

Students who pre-register will now be given access to electronic course notes, which may be printed once approximately 1-2 weeks in advance for use during the course. Hard copies of course notes will no longer be provided to pre-registered students and limited number of hard copies will be available only for on-site and transferring registrants on a first come, first served basis.

PDA EDUCATION COURSES (CONTINUED)

Recommended Practices for Manual Aseptic Processes

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 17, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 216
CPE: ACPE # 0116-0000-14-061-L04-P | 0.6 CEUs
Type of Activity: *Knowledge*

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

Faculty
To Be Determined

Establishment of a Risk Based Environmental Monitoring (EM) Program

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 17, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 347
CPE: ACPE #0116-0000-14-070-L04-P | 0.6 CEUs
Type of Activity: *Application*

This course will present information on the establishment of a risk based environmental monitoring (EM) program. It will cover both the establishment of new EM programs as well as reassessment of current EM programs to bring them into compliance with industry standards. This course will review routine EM program requirements and EM program qualification requirements. Instruction will be given on the use of risk tools for determination of microbial contamination sources in production environments and processes, and on the use of EM risk assessment tools.

Who Should Attend
Environmental Monitoring Samplers, Microbiologists, Microbiology Department Managers and Supervisors, Validation Technicians and Managers, and Quality Assurance staff responsible for risk assessments reviews will benefit from this course.

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

- Discuss global requirements for the establishment of risk based EM programs
- Utilize assessment tools available for EM risk analysis
- Perform EM risk assessments utilizing risk tools (Fishbone, FMEA, HACCP)
- Establish risk based EM programs at your company

Faculty
Marsha Stabler Hardiman, Senior Consultant, *Concordia ValSource, LLC*

Quality Metrics: Performance Indicators

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 17-18, 2016
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 510
CPE: ACPE #0116-0000-14-034-L04-P | 1.2 CEUs
Type of Activity: *Application*

A recognized industry expert will present his perspective on selecting the appropriate quality metrics, determining how best to collect the data and how to use the data to improve the Quality System (QS). The kinds of processes to be discussed

PDA EDUCATION COURSES (CONTINUED)

include the production process, supporting processes such as change control, training and validation, supplier processes and materials management. There will also be a brief discussion of the measurement of management and business processes. There will be numerous exercises that will enable participants to develop their own set of metrics in their organization.

Who Should Attend

- Senior management with the responsibility for the QS and its continuous improvement
- Production management with the responsibility for the quality of core process and production
- QA management with the responsibility to assist senior management in its responsibilities for the QS and for collecting and analyzing the quality metrics, and presenting them in usable form

Learning Objectives

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

- Identify what quality metrics or performance indicators your operation needs
- Collect and analyze the appropriate data in the most cost effective way
- Use data collected and analyzed to drive continuous improvement of the QS

Faculty

Robert G. Kieffer, PhD, President, *RGK Consulting*

Process Validation and Verification: A Lifecycle Approach

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 17-18, 2016
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 320
CPE: ACPE # 0116-0000-14-071-L04-P | 1.2 CEUs
Type of Activity: *Application*

This course is designed to explain and facilitate the implementation of process validation and continued process verification 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, technology transfer and scale-up, and documentation/knowledge management.

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 the 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 validation
- 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

Faculty

To be Determined

Clean Room Design, Contamination Control and Environmental Monitoring for Controlled Environments

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 18, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 177
CPE: ACPE # 0116-0000-14-018-L04-P | 0.6 CEUs
Type of Activity: *Knowledge*

This lecture will provide the attendees with a comprehensive understanding of clean room design as it applies to ongoing operation, as well as the knowledge to develop a contamination control strategy and implement an environmental monitoring program for controlled environments. Case studies and practice failure investigations will be used to demonstrate common errors to avoid as well as best practices to implement.

The participants will gain an understanding of how design, control and monitoring work together to provide the required manufacturing environment, which will allow the participants to identify opportunities for improvement within their companies. Participants will also learn how to investigate excursions when they occur.

Who Should Attend

Technicians, managers and directors in architecture, engineering, quality assurance, and environmental monitoring will benefit from this course.

PDA EDUCATION COURSES (CONTINUED)

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

- Define the regulatory requirements for the U.S. and EU controlled environments
- Identify elements of clean room design critical to successful operation
- Explain how a contamination control program complements the environmental monitoring program
- Determine the key elements in a contamination control program
- Identify sampling locations for the environmental monitoring program
- Investigate environmental monitoring excursions and identify potential root causes

Faculty
Robert Ferer, Practice Lead, Engineering and Operations, *Quality Executive Partners (QxP), Inc.*

Process Simulation Testing for Aseptically Filled Products

Location: JW Marriott San Antonio Hill Country | San Antonio, TX
Date: March 18, 2016
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: PDA # 374
CPE: ACPE # 0116-0000-14-059-L04-P | 0.6 CEUs
Type of Activity: *Knowledge*

This course, which is based on a revised PDA Technical Report covering 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 aseptic process simulation study aspects, including run number and frequency, inclusion of intervention, worst case scenarios, bracketing approaches, incubation, inspection, acceptance criteria and investigation
- 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

Faculty
Marsha Stabler Hardiman, Senior Consultant, *Concordia ValSource, LLC*

As usual, *PDA Annual* refreshed me, updated me and allowed me to benchmark with my peers. It also gave me the chance to network with colleagues and catch up with old friends. It is a not-to-be-missed event!

– KAREN GINSBURY, *PCI Pharma*

2016 PDA Annual Meeting (March 14-16) and 2016 PDA Manufacturing Science Workshop (March 16-17)

March 14-16, 2016 | San Antonio, TX

JW Marriott San Antonio Hill Country Resort & Spa

Exhibition: March 14-15 | Workshop: March 16-17 | Courses: March 17-18

Four easy ways to register –

Click: pda.org/2016annualmeeting
Fax: +1 (301) 986-1093 (USA)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 150
Bethesda, MD 20814 USA
Call: +1 (301) 656-5900 ext 115

Print

PDA Parenteral Drug Association

1 Contact Information

PDA Membership Number:

☐ **Check here to become a member and receive the member price for this event.** (Add $259 to your total.)

Prefix First Name Last Name

Job Title Company

Business 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.)

Special Dietary Requirements (Please be specific):

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

2 Premier Package | CONFERENCE & WORKSHOP Registration | March 14-17, 2016

Please check appropriate fee (US$).

Save up to $750!	Member	Nonmember
Before January 11, 2016	☐ $ 2,545	☐ $ 2,804
January 11 – February 11, 2016	☐ $ 2,995	☐ $ 3,254
After February 11, 2016	☐ $ 3,245	☐ $ 3,504

3 CONFERENCE Registration | March 14-16, 2016

Please check appropriate fee (US$).

	Before Jan. 11, 2016	Jan. 11 – Feb. 11, 2016	After Feb. 11, 2016
PDA Member	☐ $ 1,895	☐ $ 2,295	☐ $ 2,495
Nonmember	☐ $ 2,154	☐ $ 2,554	☐ $ 2,754
Government/Health Authority			
Member	☐ $ 700	☐ $ 700	☐ $ 700
Nonmember*	☐ $ 800	☐ $ 800	☐ $ 800
Academic			
Member	☐ $ 700	☐ $ 700	☐ $ 700
Nonmember*	☐ $ 800	☐ $ 800	☐ $ 800
Student			
Member	☐ $ 280	☐ $ 280	☐ $ 280
Nonmember*	☐ $ 310	☐ $ 310	☐ $ 310

* For this member type or discounted rate, online registration is not available and must be faxed in.

4 WORKSHOP Registration | March 16-17, 2016

Please check appropriate fee (US$).

2016 PDA Manufacturing Science Workshop	☐ $ 800

5 NETWORKING Registration

Please check appropriate fee (US$).

Sunday, March 13, 2016 **7:00 a.m. – 10:00 a.m.** **10th Annual Walk / Run Event** ***Benefiting Fisher House Incorporated*** Walk/Run for a cause with PDA, colleagues, family and friends.	# of tickets: _____	☐ **$ 45 per registered attendee or guest.** All net proceeds will go to charity.
Tuesday, March 15, 2016 **6:00 p.m. – 8:00 p.m.** **65th Anniversary Gala Event** All full conference attendees are invited to attend. Guests are welcome to attend at $70 per person.	# of tickets: _____	☐ **$ 70 per person.**
	Total Due	$

6 COURSE Registration | March 17-18, 2016

See 2016 Annual Meeting Course Series registration form for more information.

7 Payment Options

All cards are charged in US$.

Group Registration: Register 4 people from the same organization as a group (at the same time) for the CONFERENCE and receive the 5th registration free. Other discounts cannot be applied. All forms MUST be faxed in together.

☐ By Credit Card – Clearly indicate account number, 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 (Billing address must match credit card statement)

City State Zip

PDA Federal Tax I.D. #52-1906152

Country

Wire Transfer Payments: If you require wire transfer, please contact registration@pda.org.

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 **January 13, 2016,** 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 non-member substituting for a member, you will be required to pay the difference in the non-member fee. If you are pre-registering as a subsitute attendee, indicate this on the registration form. **REFUNDS:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Conference/Workshop:** If your written request is received on or before **January 13, 2016**, 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. 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. **PLEASE NOTE THAT PHOTO ID WILL BE REQUIRED IN ORDER TO PICK UP BADGE MATERIALS ON-SITE. THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS. RECORDING/PHOTO RELEASE:** By registering for these events, I authorize PDA to record and photograph me and to use the recordings/photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the recordings/photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership. Tape recordings are prohibited at all PDA conferences.

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

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2016 Annual Meeting Course Series

March 17-18, 2016

JW Marriott San Antonio Hill Country | San Antonio, TX

Four easy ways to register –

Click: pda.org/2016AnnualCourses
Fax: +1 (301) 986-1093 (USA)
Mail: PDA Global Headquarters
4350 East West Highway, Suite 150
Bethesda, MD 20814 USA
Call: +1 (301) 656-5900 ext 115

Print

PDA® Parenteral Drug Association

1 Contact Information

PDA Membership Number:

Prefix | Name (Last, First, MI)

Job Title | Company

Business 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.)

☐ **Check here to become a member and receive the member price for this event.** (Add $259 to your total.)

2 March 17-18, 2016

Please check appropriate fee (US$).

	Price On or Before February 1, 2016				Price After February 1, 2016			
	Standard		Government/Health Authority/Academic		Standard		Government/Health Authority/Academic	
	Member	Nonmember	Member	Nonmember*	Member	Nonmember	Member	Nonmember*
PDA #216 Recommended Practices for Manual Aseptic Processes (March 17)	☐ $ 985	☐ $ 1,255	☐ $ 600	☐ $ 700	☐ $ 1,095	☐ $ 1,395	☐ $ 600	☐ $ 700
PDA #347 Establishment of a Risk-Based Environmental Monitoring Program (March 17)	☐ $ 985	☐ $ 1,255	☐ $ 600	☐ $ 700	☐ $ 1,095	☐ $ 1,395	☐ $ 600	☐ $ 700
PDA #510 Quality Metrics: Performance Indicators (March 17-18)	☐ $ 1,525	☐ $ 1,795	☐ $ 950	☐ $ 1,050	☐ $ 1,695	☐ $ 1,995	☐ $ 950	☐ $ 1,050
PDA #352 Sterile Pharmaceutical Dosage Forms (March 17-18)	☐ $ 1,525	☐ $ 1,795	☐ $ 950	☐ $ 1,050	☐ $ 1,695	☐ $ 1,995	☐ $ 950	☐ $ 1,050
PDA #374 Process Simulation Testing for Aseptically Filled Products (March 18)	☐ $ 985	☐ $ 1,255	☐ $ 600	☐ $ 700	☐ $ 1,095	☐ $ 1,395	☐ $ 600	☐ $ 700
PDA #177 Clean Room Design, Contamination Control and Environmental Monitoring for Controlled Environments (March 18)	☐ $ 985	☐ $ 1,255	☐ $ 600	☐ $ 700	☐ $ 1,095	☐ $ 1,395	☐ $ 600	☐ $ 700

* For this member type or discounted rate, online registration is not available and must be faxed in.

3 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 (Billing address must match credit card statement)

City | State | Zip

Country

PDA Federal Tax I.D. #52-1906152

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Register before January 11, 2016 and save up to $600!

The Parenteral Drug Association presents the...

2016 PDA Annual Meeting

Harness the Power of Innovation to Improve Access to Novel Therapies

March 14-16, 2016 | San Antonio, TX

JW Marriott San Antonio Hill Country

Exhibition and Sponsorship Opportunities

The *2016 PDA Annual Meeting* will provide your company with the premier opportunity to gain access to and network with hundreds of key decision makers from the biopharmaceutical science and manufacturing industry. Align your company with leading industry minds and world class content by exhibiting at and/or sponsoring the industry's leading conference and exhibition. Extended, dedicated Exhibit Hall hours will allow ample time for information exchange with attendees from companies such as *Genentech, Eli Lilly, Pfizer, Amgen, GlaxoSmithKline, Abbott, Roche, Novartis, Merck* and others. In addition, many high-profile, cost-effective sponsorship options are available to help raise your company profile, build brand awareness, and differentiate your company from your competitors.

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 | Email: hall@pda.org

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