2018 PDA Annual Meeting
Agile Manufacturing Strategies: Driving Change to Meet Evolving Needs

Register by January 8, 2018 and save up to $600!

NEW MEETING FORMAT FOR 2018 – See what’s changing! Read more on page 4.

March 19-21, 2018 | Orlando, FL
Exhibition: March 19-21
2018 PDA Manufacturing Intelligence Workshop: March 21-22
2018 PDA Annual Meeting Course Series: March 22-23
#PDAANNUAL

This preliminary schedule-at-a-glance is current as of December 15, 2017

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS
A MESSAGE FROM THE PROGRAM CO-CHAIRS

Dear Friends, Colleagues, and Peers:

As the Co-chairs of the Program Planning Committee, we invite you to attend the 2018 PDA Annual Meeting taking place at the Loews Sapphire Falls in Orlando, Florida, March 19-21. This exceptional Conference provides the ideal venue for gaining the latest information on a broad range of topics related to processing, manufacturing, and quality control. We invite you to share with colleagues from around the world best practices on the application of novel approaches for the development and commercialization of bio/pharmaceutical products.

The theme of this year’s Conference, Agile Manufacturing Strategies: Driving Change to Meet Evolving Needs, emphasizes a forward-looking view into the future of bio/pharmaceutical science and technology. The Program Planning Committee has worked diligently over the past several months to develop a comprehensive and informative program, directly aligned with this important theme, and covering a wide variety of critically important industry topics. It has been a key focus for the Committee to ensure that the Conference provides valuable, “need to know” information for professionals both experienced and new to the industry and representing both large and small molecule-based pharmaceuticals.

Thus, the invited speakers will focus their presentations on the end-user’s/patient perspective, innovative manufacturing strategies, disruptive technologies, and product value chain logistics. The increased use of big data, artificial intelligence, and robotics in the industry will also be explored. As part of our new Conference format, concurrent Interest Group meetings on select topics will take place at the same time as the breakout sessions, giving attendees additional choices and the chance to engage in in-depth discussions and ask questions on topics of specific interest to them. Poster sessions will feature presenters available and excited to discuss their latest research.

Don’t miss the Exhibit Hall where vendors and suppliers will showcase their latest technologies and offer solutions to current and future pharmaceutical manufacturing challenges.

Last but not least, there will be ample opportunities for peer-to-peer discussions during the breaks and social events, which we have augmented in 2018! PDA’s Annual Meeting is one of the “can’t miss” events for 2018, offering a multifaceted look into the future of pharmaceutical manufacturing.

On behalf of the Program Planning Committee, the presenters, exhibitors, and the PDA team, we can’t wait to meet you in Orlando!
GENERAL INFORMATION

For specific information on the 2018 PDA Manufacturing Intelligence Workshop, turn to page 14.

REGISTER NOW
Online: pda.org/2018Annual
Fax: +1 (301) 986-1093 (USA)
Questions? Call Registration at +1 (301) 656-5900 ext. 115

VENUE
Loews Sapphire Falls
6601 Adventure Way
Orlando, FL USA 32819
Phone: +1 (407) 503-5000
Website: www.loewshotels.com/sapphire-falls-resort
Rate: Single/Double: $252.00, plus applicable state and local taxes
Cut-Off Date: Friday, February 16 (A PDA block of rooms are available 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 email the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

ALERT: ACPE and the National Association of Boards of Pharmacy developed the Continuing Pharmacy Education (CPE) Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

2018 PDA Annual Meeting
ACPE # 0116-0000-17-035-L04-P | 1.35 CEUs
Type of Activity: Knowledge

LEARNING OBJECTIVES
At the completion of this activity, the participant will be able to:

- Interpret the latest trends in microbiological and adventitious agent control strategies
- Identify advanced analytical approaches that can be applied for quality control and real-time release
- Describe delivery system design and manufacturing logistics for patient-centered therapies and precision medicine
- Find best practices for identifying and applying new technologies

WHO SHOULD ATTEND
Job Functions
Scientist | Executive and Mid-Level Management | Project Management | Technical Services | Supply Chain | Manufacturing Application | Risk Management

Departments
Manufacturing | Product Development | Quality | Research & Development | Engineering | Laboratory | Science | Information Technology | Validation | Training

CONFERENCE REGISTRATION HOURS
Sunday, March 18: 4:00 p.m. – 7:00 p.m.
Monday, March 19: 9:00 a.m. – 5:00 p.m.
Tuesday, March 20: 7:30 a.m. – 5:30 p.m.
Wednesday, March 21: 7:30 a.m. – 3:15 p.m.

COURSE REGISTRATION HOURS
Thursday, March 22: 7:30 a.m. – 4:00 p.m.
Friday, March 23: 7:30 a.m. – 4:00 p.m.

DRESS/ATTIRE
Business casual attire is recommended for all events. 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 registration@pda.org.

CONTACT INFORMATION
Conference Inquiries
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Education Course Series Inquiries
Stephanie Ko, Senior Manager, Lecture Education
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In response to attendee feedback, PDA is debuting a NEW meeting format at the 2018 PDA Annual Meeting. This format is designed to better meet the needs of our attendees. Most notably:

- The Conference will now begin with the Opening Plenary at 1:00 p.m. on Monday, March 19
- The Grand Opening Celebration will kick off in the Exhibit Hall at 5:00 p.m. on Monday, March 19 – take advantage of your first opportunity to see the latest products and services and meet with exhibitors!
- Interest Group sessions will be held at the same time as the breakout sessions, giving attendees more sessions from which to choose during the day and allowing for more free time in the evening
- The Closing Reception will take place on Wednesday, March 21 at 7:00 p.m. – Be sure to stay and celebrate with us!

SUNDAY, MARCH 18 – MONDAY, MARCH 19

SUNDAY, MARCH 18

1:00 p.m. – 7:00 p.m.
Exhibitor Set Up

4:00 p.m. – 7:00 p.m.
Registration Open

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

MONDAY, MARCH 19

7:00 a.m. – 4:00 p.m.
Exhibitor Set Up

9:00 a.m. – 5:00 p.m.
Registration Open

1:00 p.m. – 1:30 p.m.
Welcome and Opening Remarks from PDA Leadership and the Meeting Planning Committee Co-Chairs
Rebecca Devine, PhD, Biopharmaceutical Consultant and Chair, Board of Directors, PDA
Richard M. Johnson, President and CEO, PDA
Ghada Haddad, MBA, Executive Director, Global GMP Auditing, Merck & Company/Merck Sharp & Dohme
Morten Munk, Global Technology Partner, NNE
MONDAY, MARCH 19 (CONTINUED)

1:30 p.m. – 3:00 p.m.
P1: Patient Perspective – Future Visions

Session Description: All participants at this Conference are in some way involved in providing pharmaceuticals to patients. It is a privilege and offers a clear purpose to be part of a community that has the possibility to make an instrumental difference to the individual patient and to society in general. This opportunity to make a difference comes with substantial responsibility to ensure that we do our utmost to meet the expectations of the patients and healthcare professionals, who rely on us in providing safe and effective pharmaceuticals. This session gives a clear perspective of the individuals that are ultimately benefiting from our daily efforts.

1:30 p.m. – 2:00 p.m.
Clinician Perspective on Future Patient Therapies
Stephen Kingsmore, MD, DSc, President and CEO, Rady Children’s Institute for Genomic Medicine

2:00 p.m. – 2:30 p.m.
Patient Perspective
Lori Richter, Senior Consultant, ValSource LLC

2:30 p.m. – 3:00 p.m.
Questions and Answers/Discussion

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

3:30 p.m. – 5:00 p.m.
P2: Disruptive Technology and the Future of Medicine

Session Description: Today’s healthcare is not sustainable due to the rising costs of treatment, aging populations, and healthcare worker shortages. The future of medicine will be innovative, patient focused, and digital. Our industry and the regulatory framework that governs our products and services must overcome technical and cultural challenges by embracing disruptive technologies that make healthcare more effective by putting patients in the center of healthcare strategies, digitizing information to grow our understanding of disease and treatment, and shifting healthcare from a “break and fix” mentality to one of prevention. This session will explore the trends in technology and how they will alter our current view of the healthcare system and the medicines we make to improve the lives of patients. We will also examine how companies must build their cultures of innovation in order to deliver on this promise.

3:30 p.m. – 4:00 p.m.
Company Dynamics
Steven J. Spear, Senior Lecturer, System Dynamics, Massachusetts Institute of Technology (MIT)

4:00 p.m. – 4:30 p.m.
Regulatory Perspective on New Technologies
Regulatory Representative Invited

4:30 p.m. – 5:00 p.m.
Questions and Answers/Discussion

5:00 p.m. – 6:30 p.m.
Grand Opening Celebration in Exhibit Hall
TUESDAY, MARCH 20

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

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

8:30 a.m. – 10:00 a.m.
P3: Genomic Profiling

**Session Description:** Our understanding of genomics is dramatically changing healthcare, leading the way to personalized care. Advances in the field of DNA sequencing and the ability to collect and analyze large amounts of data quickly has played a critical role in the evaluation of research. Using genomic profiling, it is possible to map an individual’s unique genomic profile, providing physicians with invaluable information to help determine the best treatment. It can be used to find out why certain people get diseases while others do not or why people react differently to the same drug. Likewise, this data can help biotech companies make informed decisions in their R&D investments. This session will explore the role of genomic profiling as a tool for identifying the potential risk of certain health conditions and application of treatment strategies/therapies that are tailored to the genetic profile of each patient.

8:30 a.m. – 9:00 a.m.
Learning from Kymriah, a CAR-T Therapy that Targets B Cell Malignancies
David Lebwohl, MD, Franchise Global Program Head, CAR-T Team, Novartis Oncology Global Development Unit, Novartis Pharmaceutical Corporation

9:00 a.m. – 9:30 a.m.
Industry Perspective on Genomic Profiling
Industry Presenter Invited

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

9:45 a.m. – 6:30 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall
**TUESDAY, MARCH 20 (CONTINUED)**

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

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**Session Description:**
The IT revolution is evident all around us, but the emphasis has mostly been on the T, the technology. It is time to recast our gaze to focus on the I, the information. Perhaps this information really means insight. Has your company made this transition and begun treating data as an asset and not a cost? Are you getting insight out of information? Responses vary across pharma manufacturing companies, as do those companies’ abilities to harness information in novel ways to produce insights of significant value. This session will explore examples of where data is being put to new uses to solve difficult real-world problems. Different strategies, what has been learned, and what challenges have been encountered, some of which might not yet have been overcome, will be key takeaways. There is a revolution underway in IT, but it is just as much in the information side of the acronym as in technology.

**Session Description:**
The face of pharmaceutical manufacturing has changed drastically in the past two decades. Not only from a technological and scientific standpoint, but also with regard to the regulatory and political environment. Shorter patent protection, lower price premiums, and increasing barriers to reimbursability have created a market where faster development, smaller volumes, and expanding levels of customization are not only more common, but also more desirable. Deciding when to invest in house and when to leverage a third party has become a critical business decision as limited resources must be carefully divided among a wider range of needs. Third party companies are being actively leveraged across all stages of the product lifecycle, from development to launch and through product end of life and from the labs to manufacturing. This session will explore a few of those scenarios, sharing experiences, and points to consider when making these critical decisions.

**Session Description:**
This session will have short presentations on current issues in process validation, followed by an open discussion. A small panel of SMEs will be assembled to lead the open discussions.

**Session Description:**
Annex I includes a controversial paragraph on the integrity test pre-use/post sterilization. This paragraph causes severe problems within the industry. Since the Annex I revision will be published, we need to review the paragraph posted in the revised Annex I and see what actions are required to be taken. We will also have a discussion about new initiatives regarding PUPSIT:

- Statement by filter manufacturers
- Blocking test proposal within PDA Education
- MOU with BPOG to work together on PUPSIT

12:15 p.m. – 1:45 p.m.
Networking Luncheon in Exhibit Hall
**TUESDAY, MARCH 20 (CONTINUED)**

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

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**Session Description:**
Continuous manufacturing offers compelling benefits with respect to costs, process flexibility, and capacity. In fact, the 21st Century Cures Act, enacted in December 2016, authorized grants to support studying continuous manufacturing of drugs and biological products. Control strategies for these processes must also continuously provide assurance of quality, mitigating any risk to product quality because of process variations over time. This session will focus on science- and risk-based approaches to control strategies that can be implemented to monitor and ensure appropriate understanding of process dynamics and their relation to process conditions and raw material control. Tools, including model-based control, multivariate monitoring, automation, and real-time release testing, will be discussed, along with identification and rejections of non-conforming segments.

**Session Description:**
The need for improved aseptic manufacturing capabilities has led to innovations in isolator technology. To meet increasing product demand while ensuring patient safety and product quality requires new thinking in implementing aseptic processes and capabilities. To continue to manufacture effectively, it is necessary to look at systems that are reliable yet flexible. This session will showcase two different implementation strategies to improve aseptic processing capabilities. Speakers will share innovative ways to implement robotics and environmental considerations with regard to isolator technology.

**Session Description:**
With new and evolving manufacturing strategies, QRM programs are also evolving to meet new demands and, in some cases, becoming more mature. With this change in the environment, regulatory authorities are also changing and requiring more from the industry with respect to their QRM programs. In this session, we will discuss strategies in presenting a QRM program to health authorities, using actual examples and case studies. Participants will also be working in teams to develop audit strategies and responses to practice scenarios. Examples will be presented that address both what the auditor is expecting and how the auditee should plan on responding. This will include both proper and improper use of QRM in audit responses. The session will end with lively dialogue involving the participants and the presenters as both groups work through the scenarios.

**Session Description:**
PDA’s Biotechnology Advisory Board (BioAB) has recently changed the name and scope for the Biotechnology Interest Group (IG). The IG was renamed to Biopharmaceutical Manufacturing. This focus better aligns with PDA’s overall mission to advance manufacturing science and technology. This session represents the inaugural meeting for the newly formatted Biopharmaceutical Manufacturing Interest Group (IG).

The session will cover:
- Outlining the objective and mission of the Biopharmaceutical Manufacturing IG
- Soliciting input from participants on future directions and focus areas for the IG

Following this introductory discussion, the session will focus on the latest developments in manufacturing science and technology for biopharmaceutical products, including advanced cell and gene therapies. The content will include both presentation and time for interactive
### TUESDAY, MARCH 20 (CONTINUED)

**INNOVATIVE MANUFACTURING STRATEGIES**

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<td>IG3: Quality Risk Management (continued)</td>
<td>IG4: Biopharmaceutical Manufacturing (continued)</td>
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Dialogue addressing topics related to process optimization to streamline operations, improvements to increase efficiency and reduce costs, and approaches for achieving the highest level of biopharmaceutical product quality.

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

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### 2018 PDA ANNUAL MEETING

**EXHIBITION AND SPONSORSHIP OPPORTUNITIES**

The 2018 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 Biogen, 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  
Tel: +1 (240) 688-4405 | Email: hall@pda.org

**Alison Caballero**, Senior Sales Coordinator  
Tel: +1 (301) 656-5900 ext. 135 | Email: caballero@pda.org
### TUESDAY, MARCH 20 (CONTINUED)

**4:00 p.m. – 5:30 p.m.**
**Concurrent Sessions**

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**Session Description:**
High production costs, patient affordability and accessibility, and maintaining an uninterrupted supply of product are primary concerns of the biopharmaceutical industry. To address these issues, the term *agile bioprocessing* might best describe the next evolution needed for biopharmaceutical manufacturing. Indeed, industry efforts are now being directed toward reducing the long development cycle times, increasing production flexibility, and eliminating processing complexities, all with an aim toward addressing current challenges. This session explores innovative approaches being considered for future biopharmaceutical manufacturing operations, with an emphasis on latest developments in continuous bioprocessing.

**Session Description:**
The healthcare industry is experiencing unparalleled change. Millions of data points are generated throughout the end-to-end supply chain that can be converted to knowledge and understanding that leads to meaningful and timely action to improve manufacturing processes and drive organizational efficiency. A comprehensive digital strategy and structured data analytics can explore techniques such as visualization, modeling, automation, machine learning, and artificial intelligence to dematerialize manufacturing processes and facilities and drive productivity through fewer errors, higher output, and improved quality, safety, and speed. This session will explore case studies where companies have advanced their digital strategy to deliver meaningful value and advancements to the business.

**Session Description:**
The session will introduce the first program for the Cell and Gene Therapy Interest Group (IG). This session will:
- Outline the objectives and mission of the Cell and Gene Therapy IG
- Provide a 30-minute presentation on risk assessment for aseptic processing for cell therapy. This presentation will be a case study and set of recommendations for the establishment of an effective aseptic processing verification program for these innovative products.

**Session Description:**
The Facilities and Engineering Interest Group (IG) covers many specific technical interests within the industry as they relate to manufacturing facilities and engineering capabilities. There has been a tremendous amount of discussion around aging facilities the past couple of years, so at this meeting the focus will shift to look at innovation. During the B2 session, we heard about two different approaches to improving aseptic manufacturing capabilities. In this IG session, we will continue to talk with those speakers to take a deeper look at their presentations to learn more about their specific examples.

**5:30 p.m. – 6:30 p.m.**
**Happy Hour in the Exhibit Hall**
WEDNESDAY, MARCH 21

7:30 a.m. – 3:15 p.m.
Registration Open

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

8:30 a.m. – 10:00 a.m.
P4: Increasing Capacity and Capability without Increasing Costs

**Session Description:** In the past, capacity and capability increases meant lengthy, but especially cost-intensive expansions of rigid production and process infrastructures. New technology platforms, like single-use processes, create the ability to increase or utilize the current capacity in a more flexible, but also more efficient way. The new process technologies furthermore enable new process models such as continuous processing. The factors listed will change our current thinking of investments to be made, capacity flexing, and capacity location, to name a few. Examples of such innovative production and processing platforms will be presented as well as the benefits of such.

8:30 a.m. – 9:00 a.m.
Transforming Operations with Next-Generation Biomanufacturing
Arleen C. Paulino, Vice President, Singapore Site Operations, Amgen Inc.

9:00 a.m. – 9:30 a.m.
Improving Operational Performance Using a Resilience Engineering Approach: A Case Study
Amy D. Wilson, PhD, Director, Global Human Performance, Biogen

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

8:30 a.m. – 9:00 a.m.
2019 Annual Meeting Exhibit Space Draw Meeting

9:45 a.m. – 1:45 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break and Poster Presentations in Exhibit Hall
## WEDNESDAY, MARCH 21 (CONTINUED)

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

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<td><strong>A4:</strong> Implementing Manufacturing Innovation</td>
<td><strong>B4:</strong> Addressing Unique Challenges of Patient-Centric Supply Chain Needs</td>
<td><strong>IG7:</strong> Visual Inspection of Parenterals</td>
<td><strong>IG8:</strong> Combination Products</td>
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**Session Description:**
Innovation in manufacturing should be at the heart of our efforts to ensure the sustained supply of better, safer medicines to patients. Yet, our industry is very slow in adopting the wealth of new manufacturing technologies available. This session will discuss strategies for successful implementation of innovative technologies in pharmaceutical manufacturing, focusing on challenges, success factors, and key leamings. Presentations will cover the technical, cultural, and leadership aspects of implementation.

**Session Description:**
With the recent approval(s) of (a) CAR-T therapies in the U.S. and the explosion in the research into these types of therapies, there are more than 300 trials listed on ClinicalTrials.gov and more than 40 active studies. CAR-T is not the only patient-centric therapy being developed and, with this increase in active clinical studies, there is greater attention on managing the supply chain for these types of products. Hear stories from leaders in the personalized medicine space on how they are approaching the challenges of patient identity, supply chain security, cost, speed, importation, exportation, and other challenges unique to these programs.

**Session Description:**
This Interest Group session will focus on the inspection of injectable products, specifically those considered “difficult to inspect” such as lyophilized powders, suspensions and protein solutions, and those in amber glass or plastic containers. A review of the recently published PDA Technical Report on this subject will be included in the agenda. A brief presentation reviewing relevant recalls, warning letters, and 483 observations will be given followed by a moderated discussion on inspection topics of interest to those in attendance. Past discussions have included current experience with USP <790> and <1790>, selection and training of inspectors who perform manual inspection, industry benchmarks for inspection practices, and inspection results.

**Session Description:**
This session will include a discussion of the concepts, expertise, expectations, and requirements for a pharmaceutical company to develop, manufacture, and market a combination product. Topics will include areas, such as:
- Design Controls
- Mechanical/Electronic Engineering
- Risk Management
- Human Factors Engineering
- Device Software Engineering, validation and controls
- Mobile Medical Applications
- Medical Device Reports (MDRs)
- Device Purchasing Controls
- Change Management for devices
- Functional Stability
- Drug Compatibility

This session will help attendees gain an appreciation for the challenges of successfully developing, manufacturing, and marketing a combination product within the pharmaceutical company environment.

12:15 p.m. – 1:45 p.m.
Networking Luncheon and Passport Raffle in Exhibit Hall
WEDNESDAY, MARCH 21 (CONTINUED)

1:45 p.m. – 3:15 p.m.
P5: Personalized Medicine

Session Description: Until now, most medical treatments have been designed for the “average patient.” Because of this “one-size-fits-all” approach, treatments can be very successful for some patients, but not for others. Precision medicine, on the other hand, is an innovative approach that considers individual differences in people’s genes, environments, and lifestyles. It gives medical professionals the resources they need to target the specific treatments of the illnesses we encounter, further develops our scientific and medical research, and keeps our families healthier. Advances in precision medicine have already led to powerful new discoveries and several new treatments that are tailored to specific characteristics, such as a person’s genetic makeup or the genetic profile of an individual’s tumor. This is helping transform the way we can treat diseases such as cancer; for instance, patients with breast, lung, and colorectal cancers, melanomas, and leukemias routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

In the last few years, we have seen a rapid development of new methods using immunotherapies in treating different types of cancer. By combining immunotherapy with other types of treatment, an increase in the effectiveness may be accomplished. Newer types of immune treatments are now being developed, and they will affect how we treat cancer in the future. This session will explore more about the status of where pharma development is today as well as an example of a successful research.

1:45 p.m. – 2:15 p.m.
Personalized Cancer Vaccines
Rainer Mueller, PhD, Project Leader Custom Biotech, Vice President, Roche Diagnostics GmbH

2:15 p.m. – 2:45 p.m.
Polio Virus Vaccine Trial
Matthias Gromeier, MD, Professor, Department of Neurosurgery, Duke University Medical School

2:45 p.m. – 3:15 p.m.
Questions and Answers/Discussion

3:15 p.m.
Closing Remarks and Adjournment from the Meeting Planning Committee Co-Chair
Ghada Haddad, MBA, Executive Director, Global GMP Auditing, Merck & Company/Merck Sharp & Dohme

7:00 p.m. – 10:00 p.m.
Closing Reception
2018 MANUFACTURING INTELLIGENCE WORKSHOP | MARCH 21-22

From March 21-22, PDA is sponsoring the first PDA Manufacturing Intelligence Workshop. This Workshop will provide a venue for obtaining the latest information on the development of bio/pharmaceutical big data and insights at the shop floor. The forum is ideal for learning how the industry is developing its capacity to better employ and advance the use of big data in manufacturing and supply chain management.

The Workshop Planning Committee’s goal is to design an inclusive event allowing Workshop attendees to learn and discuss the needs and challenges of managing manufacturing-related data. Acquiring an understanding of the development and implementation of big data strategies will also be a key take away. The ultimate purpose of the Workshop is to encourage participants to recognize that the holistic use of data and corresponding insights gained is an effective way to meet many of the challenges of surrounding global manufacturing in a regulated bio/pharmaceutical industry.

SESSIONS WILL FOCUS ON:
• Big data fundamentals
• Real-world case studies
• Digital quality management
• Manufacturing information models
• Top risks/challenges surrounding big data
• Challenges with big data in a highly regulated industry

Don’t miss out on this important learning opportunity. Make plans now to attend the 2018 PDA Manufacturing Intelligence Workshop.

LEARNING OBJECTIVES:
At the completion of this event, attendees will be able to:
• Assess an organization’s analytical maturity level in terms of culture, internal process readiness, analytical capabilities, and data environment to facilitate implementation of big data strategies
• Identify capabilities focused on improving operations through tighter integration, linking of physical and cyber capabilities, and taking advantage of information to provide end-to-end manufacturing intelligence
• Analyze the current state of processes, forecast optimal progress, and proactively control them based on reliable predictions to enhance predictive control
• Examine the potential impact of production-related quality and regulatory concerns as they relate to the use of big data in manufacturing and supply chain management
• Describe innovative solutions to computer system validation to introduce advanced analyses in a fashion that is useful, effective, and compliant

WHO SHOULD ATTEND
Job Function:
Scientist, Engineer, Statistician | Executive and Mid-Level Management | Project Management | Technical Services | Supply Chain | Manufacturing Application | Risk Management

Departments:
Manufacturing | Product Development | Quality | Research & Development | Regulatory Affairs | Engineering | Automation | Information Technology | Validation | Data Science | Statistics | Operational Excellence

WORKSHOP REGISTRATION HOURS
Wednesday, March 21: 7:30 a.m. – 5:00 p.m.
Thursday, March 22: 7:30 a.m. – 5:30 p.m.

For specific information on the 2018 PDA Annual Meeting, turn to page 3.

Exhibit and sponsorship opportunities are available for the Manufacturing Intelligence Workshop. Contact either David Hall at hall@pda.org or +1 (240) 688-4405 or Alison Caballero at +1 (301) 656-5900 ext. 135 or caballero@pda.org for details.
Following the 2018 PDA Annual Meeting, PDA will offer seven courses from March 22-23, which have been designed to advance your knowledge!

CONTINUING EDUCATION

Continuing Education for Pharmacists

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 email the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit.

**ALERT:** ACPE and the National Association of Boards of Pharmacy developed the CPE Monitor that allows pharmacists to electronically track their CPE credits. The CPE Monitor will reject any CPE credit requests submitted past 60 days from date of ACPE accredited activity. Always submit CPE activity claims as soon as possible and by the deadline specified on the CPE credit request form.

Continuing Education for 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 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.

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.

7:30 a.m. – 8:30 a.m.: Continental Breakfast
10:00 a.m. – 10:15 a.m.: Morning Break
12:00 p.m. – 1:00 p.m.: Lunch
2:30 p.m. – 2:45 p.m.: Afternoon Break

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

Course sponsorships are available. Contact David Hall at +1 (240) 688-4405 for details.
Recommended Practices for Manual Aseptic Processes

Location: Orlando, FL
Date: March 22, 2018
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 216
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 should be designed and carried out in order to evaluate manual aseptic processing operations.

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 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 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 their jobs
- Design a protocol for the conduct of a process simulation test for manual processing

INSTRUCTOR
Cheryl Custard, Principal/Owner, Custard Consulting Group
2018 PDA ANNUAL MEETING COURSE SERIES | MARCH 22-23

Container Closure Systems and Integrity Testing

Location: Orlando, FL  
Date: March 22-23, 2018  
Duration: 2 days  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 109  
ACPE #0116-0000-16-040-L04-P | 1.2 CEUs  
Type of Activity: Application

Utilizing lectures, instrument demonstrations, hands-on testing exercises, case studies, and interactive group discussions, you will gain insight into the fast-evolving regulatory landscape in the container closure integrity field and the latest developments in testing technologies. The course introduces a practical and meaningful methodology to construct package integrity profiles using a risk-based approach and appropriate container closure integrity testing methods.

WHO SHOULD ATTEND

This course is for parenteral drug packaging engineers and formulation scientists, laboratory scientific staff and managers, parenteral manufacturing staff, sterility quality assurance, regulatory affair scientists, CMC project management, pharmaceutical packaging component manufacturing staff.

LEARNING OBJECTIVES

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

- Define current regulatory requirements for container closure integrity verification throughout product life cycle
- Develop meaningful design requirements for maximum allowed leakage limit for various product-package types
- Describe working principles of various container closure integrity (CCI) testing techniques, with a focus on deterministic methods, such as vacuum decay, electrical conductivity and capacitance (HVLD), laser-based gas headspace analysis, and mass extraction leak test
- Develop familiarity with advanced CCI testing technologies via hands-on exercises of testing representative samples
- Illustrate testing instrument design, calibration, and qualification during instrument demonstration by industry experts
- Identify advantages and limitations of each CCI technical technique
- Select appropriate CCI testing methods for specific product-package systems
- Master CCI testing method development and validation approach
- Avoid common issues and pitfalls in CCI testing
- Formulate a comprehensive CCI testing plan throughout product life cycle in support of package integrity verification profile
- Apply risk-based approaches to develop a CCI control strategy in which various CCI testing methods are used to inform, verify, and demonstrate package integrity

INSTRUCTORS

Allison Dill, Senior Research Scientist, Eli Lilly and Company  
Lei Li, PhD, Associate Engineer Advisor, Delivery and Device R&D, Eli Lilly and Company

Sterile Pharmaceutical Dosage Forms: Basic Principles

Location: Orlando, FL  
Date: March 22-23, 2018  
Duration: 2 days  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 352  
ACPE #0116-0000-17-028-L04-P | 1.2 CEUs  
Type of Activity: Knowledge

This introductory two-day course will address cleanroom design, environmental monitoring and control, sterilization principles, manufacturing unit operations, aseptic filling, dosage form development, packaging and stability requirements, validation of aseptic processing (media fills), product specific validation, QA/QC for parenterals, and regulatory trends.

WHO SHOULD ATTEND

This course is for parenteral drug packaging engineers and formulation scientists, laboratory scientific staff and managers, parenteral manufacturing staff, sterility quality assurance, regulatory affair scientists, CMC project management, pharmaceutical packaging component manufacturing staff.

LEARNING OBJECTIVES

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

- Define current regulatory requirements for container closure integrity verification throughout product life cycle
- Develop meaningful design requirements for maximum allowed leakage limit for various product-package types
- Describe working principles of various container closure integrity (CCI) testing techniques, with a focus on deterministic methods, such as vacuum decay, electrical conductivity and capacitance (HVLD), laser-based gas headspace analysis, and mass extraction leak test
- Develop familiarity with advanced CCI testing technologies via hands-on exercises of testing representative samples
- Illustrate testing instrument design, calibration, and qualification during instrument demonstration by industry experts
- Identify advantages and limitations of each CCI technical technique
- Select appropriate CCI testing methods for specific product-package systems
- Master CCI testing method development and validation approach
LEARNING OBJECTIVES
Upon completion of this course, you will be able to:
• Describe the basic principles of cleanroom facility design, environmental monitoring, and aseptic processing
• Define the critical role of personnel in cleanroom operations
• Recall the basic principles of sterilization, including an introduction to D, Z, and F values
• Summarize the design and interpretation of media fills
• 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, sources, and testing procedures
• Summarize the CGMP regulatory and inspection trends for parenteral manufacturing

INSTRUCTORS
John Ludwig, PhD, Senior Vice President, Pfizer, Inc.
Sandeep Nema, Executive Director Pharm. R&D-Global Biologics, Pfizer, Inc.

Cleanroom Management

Location: Orlando, FL
Date: March 22-23, 2018
Duration: 2 days
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 361
ACPE #0116-0000-16-028-L04-P | 1.2 CEUs
Type of Activity: Application

This course provides practical and theoretical information on contamination control and cleanroom management. Extensive guidance will be presented for the critical daily aseptic maintenance and housekeeping functions necessary to maintain the cleanliness levels required. Topics of discussion will include rules, regulations, and discipline; the art of aseptic gowning; people and particles; methods for proper aseptic surface contamination control; repair and maintenance technologies; cleanroom supplies; training; developing a quality team; how to start-up a new facility; site selection, updates on the ISO cleanroom standards, and their applications; HVAC PQ outlines and requirements; environmental monitoring; and smoke studies.

WHO SHOULD ATTEND
This course is designed for management and technicians and will benefit experienced cleanroom personnel and newcomers alike. Emphasis is placed on new developments and methods for operating every level of cleanroom or clean zone.

LEARNING OBJECTIVES
Upon completion of this course, you will be able to:
• Assess a cleanroom training program
• Manage the daily requirements of the cleanroom
• Evaluate cleanroom supplies and garments
• Assess the efficiency and frequency for aseptic and non-aseptic cleaning methods

INSTRUCTOR
Anne Marie Dixon-Heathman, Managing Partner, Cleanroom Management Associates, Inc.

Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control

Location: Orlando, FL
Date: March 23, 2018
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 442
ACPE #0116-0000-14-060-L04-P | 0.6 CEUs
Type of Activity: Knowledge

This course is based on PDA’s most popular sterilization reference, Technical Report No. 1, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control. Since its issuance, this Technical Report has been widely utilized by industry and regulatory sterilization professionals in the development and assessment of sterilization programs across the globe. This course will provide a foundational understanding of sterilization science (microbiology and thermal science) that will then be applied in the selection of a cycle design approach, sterilization process development, process performance qualification, and ongoing process control.

WHO SHOULD ATTEND
This course is for professionals in manufacturing operations, formulation, engineering, QA/QC, product and process development, regulatory affairs, research and development, sterility assurance, technical operations, and validation.
LEARNING OBJECTIVES
Upon completion of this course, you will be able to:

- Discuss microbiology and sterilization science and apply these concepts in the development of a scientifically sound and regulatory compliant sterilization program
- Use a decision tree to select the most appropriate sterilization process based on the attributes of the load type
- Utilize the semi-log survivor curve equation in support of the development and ongoing control of the sterilization program
- Assess risk associated with the cycle phases and identification of key and critical process parameters in the development of the sterilization process for liquid and porous/hard goods loads types
- List the critical elements of process performance qualification

INSTRUCTOR
Kevin Trupp, Principal Consultant, Sterilization Technology and Compliance

Process Simulation Testing for Aseptically Filled Products

Location: Orlando, FL
Date: March 23, 2018
Duration: 1 day
Time: 8:30 a.m. – 4:00 p.m.
Course Number: 374
ACPE #0116-0000-14-059-L04-P | 0.6 CEUs
Type of Activity: Knowledge

This course, which is based on a 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.

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 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
Hal Baseman, Chief Operating Officer, ValSource LLC
2018 PDA Annual Meeting (March 19-21) and 2018 PDA Manufacturing Intelligence Workshop (March 21-22)
Loews Sapphire Falls | Orlando, FL
Exhibition: March 19-21 | Courses: March 22-23

**Premier Package | CONFERENCE & WORKSHOP Registration | March 19-22 Please check appropriate fee (US$).**

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

**ONE DAY ONLY Registration Please check appropriate fee (US$). One day registration does not include evening receptions. Reception tickets can be purchased separately.**

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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 or on or before the date noted.

**Payment Options**

All cards are charged in US$. Group Registration: Register 3 people from the same organization as a group (at the same time) for the CONFERENCE or WORKSHOP and receive the 4th 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 $ Campaign Code

Account Number Exp. Date
Name (exactly as it appears on card) Signature
Billing Address (must match credit card statement)
City State Zip

CONCLUSION: 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 required. Please be advised that if your payment or written cancellation notice is not received by January 18, 2018, your credit card will be charged the prevailing rate. SUBSTITUTIONS: If you are unable to attend, substitutions can be made at any time, including onsite for a fee of $200. If you are a non-member substituting for a member, you will be required to pay the difference in the non-member fee.

**Conference: Please check appropriate fee (US$).**

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