2018 PDA Universe of Pre-Filled Syringes and Injection Devices

Transforming Pre-Filled Systems through Innovation

Register by July 30 and save up to $600!

October 8-9, 2018 | Orlando, FL
Exhibition: October 8-9
2018 PDA Combination Products Workshop: October 10
Course Series: October 11-12
#PDAPFS

This Agenda is current as of June 29, 2018

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS
Welcome to the 2018 PDA Universe of Pre-Filled Syringes and Injection Devices. We have developed a great, well-balanced Conference that we are sure will meet – and maybe even exceed – your expectations. The topics selected will cover the broad spectrum of current issues involving pre-filled syringes and injection devices. We will be addressing key challenges that affect the variety of these devices, ranging from pre-filled syringes to injection pens, auto-injectors, and body-worn devices. We will discuss single-use, multi-use, and reusable devices.

Innovation is core to our device business. We will explore innovative products, such as new devices, new materials for syringes and their components, and new device power sources. We will look at more flexible manufacturing and assembly methods to help lower costs and provide better product. And, we will explore improved packaging both to protect the product and perhaps communicate with the patient.

“Patient Centricity” has become a mantra used to describe our development focus. Born from the human factors revolution a few years ago, patient centricity has pushed us to now focus more than ever on understanding our patients and their device needs and supplying product that will better assure they can safely and effectively deliver their medications.

No device conference would be complete today without a focus on “Connected Devices.” Although this new area will plunge many of us into the world of software and apps, the benefits could be well worth the effort. We will focus not only on both the innovation that’s happening in this arena, but also on the business case that supports such advances.

We work in a highly regulated environment. Global medical device regulations continue to evolve, and we will update you on the changing requirements around designing medical devices, manufacturing them, and then tracking their performance in the field to ensure they are safe for their intended use. The regulatory requirements may vary geographically, and those different regulatory pathways are also addressed in this year’s conference. Some special attention will be given to the upcoming EU Medical Device Regulation (MDR) changes, with a significant impact also on Combination Products. This MDR will be mandatory by May 2020, when companies will need to follow these regulations to gain approvals for their products.

This ever-popular Conference provides numerous networking opportunities. Please do not hesitate to use this venue to share experiences, new developments, regulatory considerations, challenges, and industry trends in this exciting area with your colleagues and peers and to expand your network. Please also use this opportunity to meet the suppliers who bring novel products and solutions to the industry.

On behalf of the Program Planning Committee, we would like to invite you to attend the 2018 PDA Universe of Pre-Filled Syringes and Injection Devices, October 8-9, at the Loews Royal Pacific in Orlando, FL!
For specific information on the 2018 PDA Combination Products Workshop, turn to page 11.

**REGISTER NOW**

Online:  pda.org/2018PFS  
Fax:    +1 (301) 986-1093  
Questions? Please call +1 (301) 656-5900 ext. 115

**VENUE**

Loews Royal Pacific  
6300 Hollywood Way, Orlando, FL USA 32819  
Phone:  +1 (407) 503-3000  
Website: https://www.loewshotels.com/royal-pacific-resort  
Rate: Single/Double: $205/night, plus applicable taxes.  
Cut-off Date: Thursday, September 6, 2018 (A PDA block of rooms is 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 mail the CPE credit request to the address stated on the form. Attendees must be present during the entire 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 Universe of Pre-Filled Syringes and Injection Devices  
ACPE # 0116-0000-18-018-L04-P | 1.2 CEUs  
Type of Activity: Knowledge

**LEARNING OBJECTIVES**

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

- Summarize manufacturing requirements of pre-filled syringes, injection devices, safety devices, and final drug/device combo products  
- Discuss quality standards, regulatory, and compliance concerns  
- List insights through case studies presented by industry experts  
- Discuss market, industry trends, and new technologies

**WHO SHOULD ATTEND**

Job Functions  
Manufacture of Parenteral Products | Packaging Scientists and Engineers | Stability Coordinators | Supply Chain | Logistics | Clinical Development | Business Development | Formulators | Device Engineers | Quality Engineers | Quality Professionals | Regulatory and Compliance Professionals

Departments  

**CONFERENCE REGISTRATION HOURS**

Sunday, October 7: 4:00 p.m. – 7:00 p.m.  
Monday, October 8: 7:00 a.m. – 5:15 p.m.  
Tuesday, October 9: 7:00 a.m. – 5:15 p.m.

**COURSE REGISTRATION HOURS**

Thursday, October 11: 7:30 a.m. – 4:00 p.m.  
Friday, October 12: 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**  
Jason E. Brown, Assistant Director, Programs  
Tel: +1 (301) 656-5900 ext. 131 | Email: brown@pda.org

**Registration Customer Care**  
Tel: +1 (301) 656-5900 ext. 115 | Email: registration@pda.org

**Exhibition/Sponsorship Inquiries**  
David Hall, Vice President, Sales  
Tel: +1 (240) 688-4405 | Email: hall@pda.org

**Education Course Series Inquiries**  
Stephanie Ko, Senior Manager, Lecture Education  
Tel: +1 (301) 656-5900 ext. 151 | Email: ko@pda.org
SUNDAY, OCTOBER 7 – MONDAY, OCTOBER 8

SUNDAY, OCTOBER 7

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

MONDAY, OCTOBER 8

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

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

8:15 a.m. – 8:30 a.m.
Welcome and Opening Remarks from Committee Co-Chair
David Haase, Senior Manager, Device Development, Genentech, Inc.

8:30 a.m. – 10:00 a.m.
P1: Drug Delivery Innovations that Bring Value to Both the Patient and the Business
Moderator: David Haase, Senior Manager, Device Development, Genentech, Inc.

Innovations are exciting and bring new capabilities, but they may also bring added costs. In this session, we will focus on a few of the recent connected device innovations and see how they not only bring value to the patient, but also bring real returns to the business. We will explore the patient, the pharma, the payer, and the healthcare provider perspectives.

8:30 a.m. – 9:00 a.m.
How Novel Therapies and Device Innovations are Impacting Healthcare Access and Economics
Kai Worrell, CEO, Worrell, Inc.

9:00 a.m. – 9:30 a.m.
Value-Based Healthcare
Industry Representative Invited

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

9:45 a.m. – 5:15 p.m.
Exhibit Hall Open

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

10:45 a.m. – 12:15 p.m.
P2: Overcoming the Challenges of a Cost-Controlled Environment
Moderator: Christina Braden-Moore, Marketing Director, Pharmaceutical Systems, North America & EMEA, BD Medical – Pharmaceutical Systems

Due to several market trends related to reducing healthcare costs and operating in a highly competitive market, pharmaceutical companies must find solutions that allow them to thrive in a cost-sensitive environment. Companies must continue to produce safe therapies that deliver maximum value to patients, while balancing time to market, costs, and operational effectiveness. This session will discuss solutions to manage total cost of ownership and address how to manage your overall costs to deliver products to patients.
P2: Overcoming the Challenges of a Cost-Controlled Environment (continued)

10:45 a.m. – 11:15 a.m.
Effective Collaboration between Customer and Supplier Leads to Win-Win Results Achieving New Evolving Critical Requirements and Accelerated Speed to Market
Ismael Del Pilar, Supplier Relationship Excellence Lead, Syringe Systems, Amgen Inc.
Marcelo Abad, World Wide Manufacturing Director, BD Medical – Pharmaceutical Systems

11:15 a.m. – 11:45 a.m.
Value-Based Payment Models: Balancing Outcomes and Cost for Innovative Therapies
Alexa Konstantinos, MS, Vice President, Commercial Marketing, Battelle

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

12:15 p.m. – 1:30 p.m.
Networking Lunch in Exhibit Hall – Sponsored in Part by Mitsubishi Gas

1:30 p.m. – 3:00 p.m.
Concurrent Sessions

A1: Drug Delivery within the Digital Health Ecosystem: Where do we Stand?
Moderator: Christian Helbig, Head of Strategic Business Field Glass Syringes, SCHOTT Schweiz AG

In recent years, the first connected health solutions linked to injectable drugs have been successfully launched to the market. While these launches represent a great achievement, questions remain regarding future market trends, regulatory expectations, and the overall ecosystem evolution. This session aims to reflect on the recent experiences and lessons learned with respect to the benefits delivered to patients and to the companies themselves.

1:30 p.m. – 2:00 p.m.
Connected Health: Moving Beyond The Hype
Kevin Deane, Executive Vice President, Front-End Innovation, Phillips-Medisize, a Molex Company

2:00 p.m. – 2:30 p.m.
Wearable Injectors can Improve Patient Outcomes: A Case Study from Diabetes Management that Can be Leveraged for wearable Injector Platforms for Biologic Drugs
Anil Busimi, Senior Global Product Manager, SCHOTT Schweiz AG
Edward Damiano, Professor of Biomedical Engineering, Beta Bionics

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

B1: When Packaging Becomes More Than Packaging
Moderator: Joel Cotten, Business Development Director, Aptar Pharma

From a high-level perspective, packaging must protect the injectable drugs and the intermediate injection systems until they reach the final users, mostly patients and healthcare workers. More and more frequently, the packaging of pharmaceuticals is incorporating smart innovations that serve purposes other than just the physical protection of the product. This session will present some of the most recent innovations in the market that could change the future of the packaging offering.

1:30 p.m. – 2:00 p.m.
Case Study: Implementation of an Innovative High-Speed Laser-Marking Solution on Glass Pre-Filled Syringes
Teddy Klein, Technology Program Leader, Sanofi Pasteur
Patrick Jeukenne, Board Member, Lasea

2:00 p.m. – 2:30 p.m.
Using Smart Packaging to Enhance Supply Chain Quality of Drug Delivery Devices: How Smart Primary Packaging and Object-Aware Machinery Can Lead to Better Quality Outcomes
Markus Bauss, Managing Director, SHL Connect, SHL Group
Egmont Semmler, PhD, Director, Research & Development, Groninger

2:30 p.m. – 3:00 p.m.
Questions and Answers/Discussion
MONDAY, OCTOBER 8 (CONTINUED) – TUESDAY, OCTOBER 9

3:00 p.m. – 3:45 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

3:45 p.m. – 5:15 p.m.
Concurrent Sessions

**A2: Development**
**Moderator: Brigitte Reutter-Häerle**, Vice President, Marketing/Corporate Communications, Vetter Pharma International

The development and manufacturing of drugs into delivery devices like syringes requires an intimate understanding of both the drug and the device. This session offers attendees the opportunity to learn how Control Strategy in Design Transfer can help manufacturers better understand what to control in device quality attributes, easing their pathway in transferring the device design into drug manufacturing using drug control strategy tools. Participants will also gain an understanding of GMP requirements for clinical phase 1 and 2 manufacturing of drug products and how to implement them, helping to prepare the product for later stages of development of Critical Process Parameters.

**B2: Building Clarity in Addressing Regulatory Challenges for Combination Products**
**Moderator: Fran DeGrazio**, Vice President, Scientific Affairs & Technical Services, West Pharmaceutical Services, Inc.

Pre-filled syringes and delivery devices have unique challenges from a regulatory perspective. It is critical that both drug and device requirements be understood and executed. Additionally, as new innovations get implemented, complexity is magnified. The speakers in this session will provide guidance that attendees can immediately use in addressing these issues within their own companies.

3:45 p.m. – 4:15 p.m.
**Integrating Control Strategy in Pharmaceutical and Device Development and Manufacturing for Combination Product Delivery Devices**
**Ling Li**, Senior Principal Scientist, Pfizer Inc.

4:15 p.m. – 4:45 p.m.
**Implementation of Quality Requirements in Manufacturing of Clinical Phase I/II Drug Product**
**Natascha Rivas**, Director Quality Assurance and Quality Control, Vetter Development Services USA, Inc.

4:45 p.m. – 5:15 p.m.
Questions and Answers/Discussion

3:45 p.m. – 4:15 p.m.
**Challenges and Opportunities with Applying Device Software Regulation in a Drug Setting**
**Chin-Wei Soo**, Global Regulatory Head – Combination Products and Devices, Genentech, Inc.

4:15 p.m. – 4:45 p.m.
**What’s new with Regulations? A Well-Rounded Approach to Regulatory Performance Testing for Combination Products**
**Daniel Bantz**, Technology Manager, Product Performance and Packaging, West Pharmaceutical Services, Inc.

4:45 p.m. – 5:15 p.m.
Questions and Answers/Discussion

7:00 p.m. – 10:00 p.m.
Networking Reception – Sponsored in Part by Owen Mumford and Sensile Medical

TUESDAY, OCTOBER 9

7:00 a.m. – 5:15 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

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<tr>
<th>Time</th>
<th>Session</th>
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| 7:15 a.m. – 7:40 a.m. | Impact of Excipients on Functionality  
Galen Shi, PhD, Advisor, Eli Lilly and Company  
Lian Fang, Principal Research Scientist, West Pharmaceutical Services, Inc. |
| 7:40 a.m. – 8:05 a.m. | Evaluation of a Silicone-Free Syringe and Stopper Presentation for Use in Biopharmaceutical Drug Product Development  
Caitlyn Sofa, Senior Scientist, GlaxoSmithKline |
| 8:05 a.m. – 8:15 a.m. | Questions and Answers/Discussion                                                                 |
| 7:15 a.m. – 7:40 a.m. | An Approach to Design and Develop a Platform Primary Packaging System for Parenteral Combination Products  
James Mellman, Device Manager, Novartis Pharma AG |
| 7:40 a.m. – 8:05 a.m. | Simplify Your Usability Validation: Introducing a Novel Approach for Validating Platform Device Usability  
Christoph Jordi, Senior Usability Manager, Ypsomed AG  
Allison Strochlic, Research Director, Human Factors, UL LLC/UL-Wiklund |
| 8:05 a.m. – 8:15 a.m. | Questions and Answers/Discussion                                                                 |

8:30 a.m. – 10:00 a.m.
P3: Is Your Product Genuinely Patient Centric?  
Moderator: Nic Bowman, Head of Devices CoE, Pfizer Inc.

There is increasing evidence linking patient experience with adherence rates and consequent health outcomes. So how can we achieve the best patient experience? Patient capability and preferences are already evaluated throughout the design process using human factors studies. However, patient centricity requires a deeper understanding of patients’ perspectives, motivations, and intrinsic needs. This session looks at some of the methods used to identify latent user needs, viewing the patient as an individual and enhancing patient experience in ways that patients value.

8:30 a.m. – 9:00 a.m.
When Digital Health Means Behavior Change  
Paul Upham, Senior Principal Manager, Roche/Genentech

9:00 a.m. – 9:30 a.m.
Investigating the Link between Patient Personality Dimensions and Causes of Non-Adherence  
Claire Everitt, Design Team Lead/Senior Principal Scientist, Pfizer Inc.

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion
**TUESDAY, OCTOBER 9 (CONTINUED)**

9:45 a.m. – 3:45 p.m.  
**Exhibit Hall Open**

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

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

| A3: Impact of Materials and Geometry on Primary Containers  
**Moderator:** Olivia Henderson, PhD, Principal Engineer, Amgen Inc. | B3: Quality Planning and Quality by Design  
**Moderator:** William Dierick, Fellow, Science & Technology, Terumo Europe N.V. |
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<td>A primary container’s role is to maintain quality of the dosage form by protecting against losses or additions, such as a loss of solvent, reaction with oxygen, absorption of water vapor, microbial contamination, or exposure to light. Some primary containers may also have a functional role by serving as a drug delivery device. Traditional materials, such as borosilicate glass and butyl rubber, generally provide adequate protection, but these materials may not adequately protect all drug products or be the best option for the intended storage temperature or drug delivery. This session explores alternate materials and container designs, and their impact on the drug product and drug product delivery.</td>
<td>Quality assurance of parenteral drug delivery devices and primary packaging components is an important element in the total approach to Good Manufacturing Practice (GMP). Designing for quality by using Quality by Design (QbD) concepts enables companies to achieve consistent quality in new products and processes. Using a structured approach for quality planning may provide for tools to mitigate failures and to avoid quality crises. A structured quality-planning framework supports the goals for continuous improvement and customer satisfaction. This session will explore several approaches for achieving sustainable quality for products and processes.</td>
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10:45 a.m. – 11:15 a.m.  
**Impulsively Generated Pressure and Strain Waves in Pre-Filled Syringes during Autoinjector Activation**  
Julian Jazayeri, Senior Engineer, Amgen Inc.  
Jean Christophe Veilleux, Graduate Student, California Institute of Technology  

11:15 a.m. – 11:45 a.m.  
**Flexible Primary Container Closure Systems: Reimagining the Future of Parenteral Drug Delivery**  
Akshay Kamdar, Associate Engineering Advisor / Group Leader, Eli Lilly and Company  

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

10:45 a.m. – 11:15 a.m.  
**Building a Strong Bridge to Support Device Changes or New Product Presentations**  
Sherri Biondi, Senior Director, Device Development, MedImmune  

11:15 a.m. – 11:45 a.m.  
**The Journey to a Pre-Filled on-Body Injector**  
Mark K. Lee, PhD, Chief Technology Officer, Flex Health Solutions  

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

12:15 p.m. – 1:30 p.m.  
**Networking Lunch in Exhibit Hall**
**TUESDAY, OCTOBER 9 (CONTINUED)**

### Concurrent Sessions

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<td><strong>Moderator:</strong> Nic Bowman, Head of Devices CoE, Pfizer Inc.</td>
<td><strong>Moderator:</strong> Wenzel Novak, PhD, Market Development Director, Pharma, Optima Machinery Corporation</td>
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All drug delivery devices need to pass a summative human factors test before they can be approved and released into the market. Like a driving test, a summative human factors study doesn’t necessarily represent how you drive, or indeed, intend to use a device in the real world. Human factors investigations need to be completely integrated throughout the device development process, informing the design every step of the way. This continuing evaluation should be happening right through the early investigative and concept stages, on through formative studies, and right up to the eventual summative study. This session will look into different approaches and applications of human factors in both current and innovative ways to gain insight into usability and to guide device development to deliver highly usable devices patients need.

Blockbuster strategies no longer drive the market of equipment. New approaches ask for a high variability on containers and sometimes very small batch sizes. Based on this, an increased variety of products will be handled on the same equipment. Validation, Qualification and Process set-up will become a more relevant part of the all-over availability of equipment. Historically and presently, we run a trial-and-error approach to prove a safe and reliable process. Better understanding of processes and even the use of artificial intelligence allow a modern way to reduce the risk of replication. Simulating the outcome before even testing helps to minimize cost and time. We will compare the traditional concepts and simulation strategies to improve time to market.

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<th>1:30 p.m. – 2:00 p.m.</th>
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<tr>
<td>Andreas Schneider, Innovation &amp; Business Development Manager, Ypsomed AG</td>
<td>Massimo Frasson, General Manager, Brevetti CEA Spa</td>
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<td><strong>Simulating Stressful, Emergency Use Scenarios during Injection Device Usability Tests</strong></td>
<td><strong>Industry Representative Invited</strong></td>
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<td>Allison Strochlic, Research Director, Human Factors, UL LLC/UL-Wiklund</td>
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<td><strong>Refreshment Break and Poster Presentations in Exhibit Hall</strong></td>
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TUESDAY, OCTOBER 9 (CONTINUED)

3:45 p.m. – 5:15 p.m.
P4: A New Era for Medical Devices and Combination Products: What is the Impact?  
Moderator: Manfred Maeder, PhD, Head GCA Devices & Combination Products, Novartis Pharmaceuticals AG

This session will discuss the changes to the EU MDR (Medical Device Regulation), which will alter the requirements significantly for DDCs (Drug Device Combinations = Combination Products) regarding additional submission requirements, increased involvement of notified body, and lifecycle management of products. Gain an understanding of the needs of industry and the positions of the competent authority and notified body.

3:45 p.m. – 4:15 p.m.
Industry Perspective: Changes to the EU MDR  
Marc Rohrschneider, Head, New Technologies, Novartis Pharmaceuticals AG

4:15 p.m. – 4:45 p.m.
Update on Changes to the EU MDR  
Armin Ritzhaupt, Regulatory Affairs Officer, EMA (Invited)

4:45 p.m. – 5:15 p.m.
Questions and Answers/ Discussion

5:15 p.m.
Closing Remarks from Committee Co-Chair  
Manfred Maeder, PhD, Head GCA Devices & Combination Products, Novartis Pharmaceuticals AG
2018 PDA COMBINATION PRODUCTS WORKSHOP | OCTOBER 10

Receive guidance from the real-life experiences of veteran pharmaceutical and medical device professionals detailing the challenges they have faced or are currently facing and solutions implemented with regard to the development, approval, and manufacture of drug delivery combination products. Interact with the participants in panel discussions on the issues that are important to the success of your product and your company in the future.

For more information, please visit pda.org/2018Combo

LEARNING OBJECTIVES

At the completion of this Workshop, attendees will be able to:

• Identify and prospectively address key challenges in the development, approval, and manufacture of drug delivery combination products
• Recognize potential liabilities and opportunities within their organizations
• Benchmark their own organization against others in the area
• Explain unique issues and challenges in the development, approval, and manufacture of drug delivery combination products to peers and management

WHO SHOULD ATTEND

Job Function
Manufacture of Parenteral Products | Packaging Scientists and Engineers | Stability Coordinators | Supply Chain | Logistics | Clinical Development | Business Development | Formulators | Device Development and Engineering | Quality Engineers | Quality Professionals | Regulatory and Compliance Professionals

Departments

WORKSHOP REGISTRATION HOURS

Wednesday, October 10: 7:00 a.m. – 5:15 p.m.

Exhibit and sponsorship opportunities are available for the 2018 PDA Combination Products Workshop. Please contact David Hall at hall@pda.org or +1 (240) 688-4405.

CONTACT INFORMATION

Workshop Inquiries
Jason E. Brown, Assistant Director, Programs
Tel: +1 (301) 656-5900 ext. 131 | Email: brown@pda.org

Registration Customer Care
Tel: +1 (301) 656-5900 ext. 115 | Email: registration@pda.org

Exhibition Inquiries
David Hall, Vice President, Sales
Tel: +1 (240) 688-4405 | Email: hall@pda.org
CONTINUING EDUCATION FOR PHARMACISTS

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**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. No exceptions can be given. Always submit CPE activity claims immediately following the event 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 hall@pda.org or +1 (240) 688-4405.
IDENTIFICATION AND CLASSIFICATION OF NONCONFORMITIES IN MOLDED AND TUBULAR GLASS CONTAINERS FOR PHARMACEUTICAL MANUFACTURING

Location: Orlando, FL  
Date: Thursday, October 11  
Duration: 1 day  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 283  
ACPE #0116-0000-17-032-L04-P | 0.6 CEUs  
Type of Activity: Knowledge

This course will provide manufacturers and users of glass containers with valuable knowledge related to the quality of glass containers, including the types of defects associated with glass manufacture, the development of standardized quality criteria, and sampling plans for use in the quality decision-making process.

WHO SHOULD ATTEND

Individuals involved with glass manufacture, quality control and quality assurance package engineering, manufacturing, and regulatory affairs will all benefit from attendance at these courses.

LEARNING OBJECTIVES

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

• Summarize current best practices for identification and classification of visual nonconformities in glass containers  
• Discuss the development and use of appropriate sampling plans for incoming inspection of glass containers and the appropriate application of acceptable quality limits for accept/reject decisions  
• Describe the appropriate documentation and training for personnel involved in glass in section and disposition decisions  
• Explain the importance of a partnership between glass manufacturers and the pharmaceutical company using the glass containers in establishing glass container quality specifications

FACULTY

Roger Asselta, Vice President, Genesis Packaging Technologies

TECHNICAL AND REGULATORY CHALLENGES OF DRUG DELIVERY COMBINATION PRODUCTS - PRE-FILLED SYRINGES, AUTOINJECTORS, AND INJECTION PENS

Location: Orlando, FL  
Date: Thursday, October 11  
Duration: 1 day  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 464  
ACPE #0116-0000-17-029-L04-P | 0.6 CEUs  
Type of Activity: Application

In this comprehensive course, examine the technical and regulatory challenges companies will face in the development and registration of drug delivery combination products.

WHO SHOULD ATTEND

This course will be geared toward individuals who have oversight over or actively participate on drug delivery combination product development teams. This includes project managers, and directors or managers in marketing, regulatory affairs, quality assurance, clinical affairs, and device development engineering.

LEARNING OBJECTIVES

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

• Discuss the basic elements and requirements behind the regulation of drug delivery combination products  
• Propose and choose appropriate regulatory strategies  
• Develop a set of criteria with which to assess and choose device partners  
• Explain the GMP/QSR expectations and responsibilities relevant to companies developing and manufacturing these products  
• Describe the expectations for robust risk management and human factors engineering systems in order to execute a successful development program  
• Identify the appropriate testing schemes and requirements specific to your products  
• Outline the contents of a clinical or marketing approval application

FACULTY

Lee Leichter, President, P/L Biomedical
2018 PDA UNIVERSE OF PRE-FILLED SYRINGES AND INJECTION DEVICES COURSE SERIES

ASSESSING PACKAGING AND PROCESSING EXTRACTABLES/LEACHABLES

Location: Orlando, FL  
Date: Thursday, October 11 and Friday, October 12  
Duration: 2 days  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 190  
ACPE #0116-0000-17-041-L04-P | 1.2 CEUs  
Type of Activity: Knowledge

This course will review regulations regarding the reporting, identification, and measurement of extractables/leachables from packaging materials and product contact items used in drug processing to help attendees perform a scientific-based assessment and meet regulatory expectations.

WHO SHOULD ATTEND

The course will be of significant value to personnel involved in packaging science, drug manufacturing, toxicology, drug formulation, material and component suppliers, CMC and DMF writing, regulatory affairs, analytical chemistry, and material science.

LEARNING OBJECTIVES

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

• Explain the extractables/leachables expectations in the FDA guidance, USP, ICH, ISO, CFR and other regulatory documents
• Identify what specific extractables/leachables information must be present in the CMC sections of applications for the various types of drug products (injectables, oral, etc.)
• Identify sources of extractables from packaging, including combination products and processing components/materials, such as plastics, glass, and rubbers
• Design and execute an extractables/leachables study

FACULTY

Diane Paskiet, Senior Director of Scientific Affairs, West Pharmaceutical Services  
Edward Smith, Principal Consultant, Packaging Science Resources, LLC

UNDERSTANDING PRODUCT OPTIONS, USER NEEDS, AND FILL-FINISH REQUIREMENTS FOR NESTED FORMAT SYRINGES, CARTRIDGE CONTAINERS, AND DRUG DELIVERY SYSTEMS

Location: Orlando, FL  
Date: Thursday, October 11 and Friday, October 12  
Duration: 2 days  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 546  
ACPE #0116-0000-18-008-L04-P | 1.2 CEUs  
Type of Activity: Application

Gain an in-depth understanding of the newest packaging technologies that support evolving drug and patient needs, considerations that must be taken into account, quality expectations to fulfill regulatory requirements, and how new manufacturing strategies are being applied to provide flexibility and decreased investments.

WHO SHOULD ATTEND

This course is for drug development scientists, packaging and conditioner development engineers, and device engineers, and personnel who are in manufacturing for fill-finish, QA involved in fill-finish and sterility assurance, product management, technical operations, purchasing, and brand marketing.

LEARNING OBJECTIVES

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

• Recognize all steps involved in a functioning system of drugs, containers, devices, and processes
• Distinguish and resolve potential issues in the interaction and integration of drugs, processes, containers, and delivery devices
• Evaluate the methods of analysis and create the best and quickest way of development
• Identify and address any challenges during development
• Identify all steps involved in the development of a primary packaging container and fill-finish technology
• Describe the processes and influences in minimizing risk and expediting drug launch and market entry
• Demonstrate the system to customers, partners, and colleagues to identify potential challenges
• Explain the needs of all components and outline processes to colleagues
• Defend needs and timelines to the organization

FACULTY

Wenzel Novak, Market Development Director, Optima Machinery  
Tibor Hlobik, Sr. Director Product Management Prefilled Systems & Delivery, West Pharmaceutical Services, Inc.  
Horst Koller, CEO, HK Packaging Consulting GmbH
THE MANUFACTURE OF STERILE PHARMACEUTICAL PRODUCTS USING BLOW-FILL-SEAL TECHNOLOGY

Location: Orlando, FL  
Date: Friday, October 12  
Duration: 1 day  
Time: 8:30 a.m. – 4:00 p.m.  
Course Number: 539  
ACPE #0116-0000-18-007-L04-P | 0.6 CEUs  
Type of Activity: Application  

This course is designed to provide and evaluate recommendations specific to the operation of Blow-Fill-Seal technology for the manufacture of sterile pharmaceuticals (e.g., injectable, ophthalmic, parenteral, and inhalation drugs and medical devices).

WHO SHOULD ATTEND

This course is designed to provide a broad overview for individuals working in sterile formulation/process development, sterile manufacturing, QA/QC, microbiology, environmental monitoring, package engineering, and aseptic fill and finish.

LEARNING OBJECTIVES

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

• Describe the recommended requirements necessary to utilize blow-fill-seal (BFS) fill/finish technology
• Assess if BFS technology can be applied to new or existing pharma products
• Describe the basic principles of BFS: cleanroom facility design, environmental monitoring, and aseptic processing
• Explain the process of evaluating product contact materials, extractable profiles, and leachable risk
• Evaluate the aseptic risk of BFS in comparison to other advanced aseptic fill/finish operations: isolators and closed RABS systems
• Identify the specific qualification and validation aspects for BFS

FACULTY

Martin Haerer, PhD, Rommelag  
Tim Kram, General Manager, Rommelag

EXHIBITION AND SPONSORSHIP OPPORTUNITIES

The 2018 PDA Universe of Pre-Filled Syringes and Injection Devices offers exciting and unique sponsorship and exhibition packages designed to strengthen brand image, increase visibility, and help you connect with industry leaders. This is a must-attend event for all industry professionals involved in the development, manufacturing, marketing, or use of pre-filled syringes and injection devices. Don’t miss your chance to engage with high-quality leads from a variety of manufacturing companies!

High-profile sponsorships are available for lanyards, notepads, audience response systems, tote bags, pens, refreshment breaks, lunch, and networking reception. We can also create a customized sponsorship or exhibition package to fit your company’s unique needs and budget.

For more information about exhibit and sponsorship opportunities, please contact David Hall at hall@pda.org or +1 (240) 688-4405.
### Contact Information

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**SUBSTITUTING FOR**

(only if you are substituting for a previously enrolled colleague. The 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.)

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### Première Package | CONFERENCE & WORKSHOP Registration | Oct. 8-10, 2018

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### COURSE Registration | Oct. 11-12, 2018

**PDA #464**  Technical and Regulatory Challenges of Combination Products, Drug Delivery Products – Pre-Filled Syringes, Autoinjectors, and Injection Pens (Oct. 11)

**PDA #283**  Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing (Oct. 11)

**PDA #190**  Assessing Packaging and Processing Extractables/Leachables (Oct. 11-12)

**PDA #546**  Understanding Product Options, User Needs and Fill-Finish Requirements for Nested Format Syringes, Cartridge Containers, and Drug Delivery Systems (Oct. 11-12)

**PDA #539**  The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology (Oct. 12)

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### WORKSHOP Registration | Oct. 10, 2018

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### Payment Options

**All cards are charged in US$**

- **By Credit Card** – Clearly indicate account number, expiration date, and billing address. Please bill me: 
  - American Express
  - MasterCard
  - VISA
  - Credit Card Guarantee Only

Total amount $  

Account Number  
Exp. Date  
Signature  

Billing Address (Billing address must match credit card statement)

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### Confirmation

A confirmation email will be sent to you once payment is received. You must have this 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 **August 9, 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. If you are pre-registering as a substitute attendee, indicate this on the registration form. **REFUNDS**: Request must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted).

**REFUNDS FOR EVENTS**: If you are pre-registering as a substitute attendee, indicate this on the registration form. **After Aug. 27, 2018**, you will receive a full refund minus a $200 processing fee. After that time, no refunds will be approved. **COURSE CANCELATION**: If an event is 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. **ATTENDEE LIST**: The attendee list is shared with attendees and exhibitors and may be used to follow up on specific areas of interest after the event.

### RECORDING

Tape recordings are prohibited at all PDA Events.

### ATTENDEE LIST

The attendee list is shared with attendees and exhibitors and may be used to follow up on specific areas of interest after the event.

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**PDA Federal Tax I.D. #52-1906152**

PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event is modified or 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. **RECORDING**: Tape recordings are prohibited at all PDA Events. **ATTENDEE LIST**: The attendee list is shared with attendees and exhibitors and may be used to follow up on specific areas of interest after the event.