

The Parenteral Drug Association presents the...

2016 PDA Universe of Pre-filled Syringes & Injection Devices



October 17-18, 2016 | Huntington Beach, CA

Hyatt Regency Huntington Beach Resort and Spa

Exhibition: October 17-18 | 2016 PDA Drug Delivery Combination Products Workshop and Exhibition: October 19 | Courses: October 20-21

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Exploring the latest trends in devices, connectivity,
safety and compliance

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This preliminary agenda is current as of May 16, 2016

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS



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Amgen, Inc.

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SHL Pharma

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PDA Liaison to the Program
Planning Committee

Georg Roessling, PhD

PDA Europe Liaison to the Program
Planning Committee

A MESSAGE FROM THE PROGRAM CHAIR



Olivia Henderson, PhD
Amgen, Inc.

On behalf of the Program Planning Committee, we would like to invite you to attend the 2016 PDA Universe of Pre-filled Syringes & Injection Devices from Oct. 17-18.

We have developed a well-balanced Conference that we are sure will meet your expectations. The topics selected will cover a broad spectrum of the current issues involving pre-filled syringes and injection devices.

Pre-filled syringes and injection devices are a specialized subset of pharmaceutical packages, but they have many points in common with all pharmaceutical packages and delivery devices: all are required to be manufactured under good manufacturing practices and all are required to have demonstrated safety and efficacy.

The benefits of pre-filled syringes and injection devices are that they enable more convenient doses, lower waste and less hands-on care by healthcare providers. Patient convenience is a key driver in the development of pre-filled syringes and devices, and the topics covered in the Conference reflect that demand. Various aspects of patient convenience include connected devices, innovative solutions and the regulatory requirements for getting these convenient devices approved for market.

One major facet of this year's Conference involves a scrutiny of various aspects of the connected device. Not only does the technology need to be developed, but also the question of what are best practices, and how the regulatory landscape must be navigated needs to be considered. How does the connected device affect patient behavior, and what information can we gather from the device? In addition, these devices are frequently the product of partnerships between device developers and drug developers. What are the key elements of these partnerships? These are critical topics that must be properly addressed to ensure fast and efficient drug development.

Innovation is a key element in the pharmaceutical, biotech and device industries. Innovation enables the development of new drugs and delivery devices for the treatment of critical medical needs. Innovation may take many forms, but here are several areas we are prepared to address: innovative materials for syringes, innovation for devices and innovative manufacturing equipment.

To round out the agenda, we will look at the regulatory environment. Pre-filled syringes and devices are also subject to regulatory approval before they can be marketed for patients' use. The regulatory requirements may vary geographically, and those different regulatory pathways are also addressed in this year's Conference.

The Conference offers 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. Please also use this opportunity to visit the Exhibit Hall to meet the vendors and to expand your network.

2016 PDA Universe of Pre-filled Syringes & Injection Devices**October 17-18, 2016** | Hyatt Regency Huntington Beach Resort and Spa | Huntington Beach, CA

Exhibition: October 17-18 | 2016 PDA Drug Delivery Combination Products Workshop and Exhibition: October 19 | Courses: October 20-21

GENERAL INFORMATION, REGISTRATION**Four Ways to Register**

- | | |
|-----------------|---|
| 1. Click | pda.org/2016prefilled |
| 2. Fax | +1 (301) 986-1093 |
| 3. Mail | PDA Global Headquarters
Bethesda Towers
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA |
| 4. Phone | (301) 656-5900 ext. 115 |

Venue**Hyatt Regency Huntington Beach Resort and Spa**21500 Pacific Coast Highway
Huntington Beach, CA 92648**Phone:** +1 (714) 698-1234**Website:** www.huntingtonbeach.hyatt.com**Rate:** Single: \$269 plus applicable state and local taxes.**Cut-Off Date:** Thursday, September 15, 2016 (*Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the Conference rate.*)**Continuing Education Credits**

PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits.

To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit, which will be awarded as follows:

2016 PDA Universe of Pre-filled Syringes & Injection Devices

ACPE # 0116-0000-16-011-L04-P | 1.2 CEUs

Type of Activity: Knowledge**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.**Learning Objectives**

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

- Discuss the market benefits of pre-filled syringes and injection devices
- Identify critical attributes of end-user-friendly devices
- Explain how innovation is helping patients to have a positive experience in managing their therapies and assuring compliance to dose regime
- Summarize manufacturing requirements of pre-filled syringes, injection devices, safety devices and final drug/device combo products

- Discuss quality standards and regulatory and compliance concerns
- List insights through case studies presented by industry experts
- Discuss market and industry trends and new technologies

Who Should Attend**Department**

Business Development | Marketing | Operations | Regulatory Affairs | Manufacturing | Pharmaceutical Formulation and Process Development | Procurement | CMC | Distribution | Packaging | Quality Assurance/Control

Job Function

Parenteral Product Manufacturing | Packaging Scientists and Engineers | Stability Coordinators | Supply Chain | Logistics | Clinical Development | Business Development | Formulators | Device Engineers | Quality Engineers, Quality Professionals, Regulatory and Compliance Professionals

Conference Registration Hours**Sunday, October 16:** 3:00 p.m. – 6:00 p.m.**Monday, October 17:** 7:15 a.m. – 5:15 p.m.**Tuesday, October 18:** 7:00 a.m. – 5:30 p.m.**Course Registration Hours****Thursday, October 20:** 7:30 a.m. – 4:00 p.m.**Friday, October 21:** 7:30 a.m. – 4:00 p.m.**Dress/Attire**

Business casual attire is recommended for the 2016 PDA Universe of Pre-filled Syringes & Injection Devices. 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****Wanda Neal, CMP**Senior Vice President, Programs and Registration Services
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SUNDAY, OCTOBER 16 – MONDAY, OCTOBER 17, 2016 AGENDA

Sunday, October 16, 2016

8:00 a.m. – 10:30 a.m.

PDA California Fun Run

3:00 p.m. – 6:00 p.m.

Registration Open

Monday, October 17, 2016

7:15 a.m. – 8:15 a.m.

Continental Breakfast

7:15 a.m. – 5:15 p.m.

Registration Open

8:15 a.m. – 8:30 a.m.

Welcome and Opening Remarks

Olivia Henderson, PhD, Principal Engineer, *Amgen, Inc.*, and Chair, *2016 PDA Universe of Pre-filled Syringes & Injection Devices*
Program Planning Committee

8:30 a.m. – 10:00 a.m.

P1 – Navigating the Ecosystem of Connected Health

Moderator: Olivia Henderson, PhD, Principal Engineer, *Amgen, Inc.*

Session Description: Innovation and connectivity are two watchwords that define our current times. When we combine the two in patient health, the opportunity to improve patients' health is enormous. But this new opportunity still needs to comply with regulatory standards, and this can be a difficult area through which to navigate. This session's speakers will give us insights for guiding the new technologies through the existing requirements.

8:30 a.m. – 9:00 a.m.

A Value-Creation Framework for a Smart Device Ecosystem

Sundeep Kankanala, Vice President, Research & Development, *BD Medical – Pharmaceutical Systems*

9:00 a.m. – 9:30 a.m.

Connectivity in Drug Delivery and Smart Administration: Improving Compliance, Patient Training and Supply Chain Visibility by Applying New Electronic Technologies

Markus Bauss, Managing Director, SHL Connect, *SHL Group*

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

MONDAY, OCTOBER 17, 2016 AGENDA (CONTINUED)

10:45 a.m. – 12:15 p.m.

P2 – Ensuring the Patient is the Focus of Improving Drug Delivery Devices**Moderator: Adalberto Ramirez**, Vice President, Quality, *Amgen, Inc.*

Session Description: With an increasing trend toward self-administration and treatment outside of a clinical environment, it is becoming more critical to understand the needs of the patient and ensure that drug delivery devices are designed and deployed with the patient in mind. This session will consider ways to improve patient outcomes through consideration of user needs analysis, design for affinity, human factors, training/onboarding and ways to improve patient adherence.

10:45 a.m. – 11:15 a.m.

A Branded Class I Mobile Medical App**Aaron Connor**, Consultant Engineer, Delivery Device Research & Development, *Eli Lilly & Company*

11:15 a.m. – 11:45 a.m.

Effective Patient Training and Onboarding for Wearable Injection Devices**Chris Evans**, Vice President, Global Innovation, *West Pharmaceutical Services, Inc.***Mike Siemer**, Director of Design & Engineering, *Noble*

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 Owen Mumford)

1:30 p.m. – 3:00 p.m.

Concurrent Sessions**A1 – Key Ingredients of Effective Partnerships****Moderator: Christina Braden-Moore**, Marketing Director, *BD Medical – Pharmaceutical Systems*

Session Description: Developing innovative drugs is complex and involves the seamless coordination of various industry players. This session will discuss how effective partnerships between drug and device manufacturers are critical for optimizing combination product development and time to market to ensure patients receive high-quality drug treatments.

B1 – Will Recent Advances in Secondary Packaging Help Meet the Challenges of Glass Breakage?**Moderator: Brigitte Reutter-Haerle**, Director, Corporate Marketing, *Vetter Pharma International*

Session Description: The choice of secondary packaging for today's increasingly complex compounds is crucial, requiring comprehensive expertise and sophisticated design in order to help achieve success in advanced injectable drug delivery. This is particularly true in the fill/finish and assembly process of glass cartridges when the complexity of combining primary and secondary packing can lead to defects and breakage. This session provides focus on the evolving injectable market and offers ideal solutions that help meet complex secondary packing challenges. Global market trends and recent technological advancements in design that help meet existing and un-met needs as well as improvements in handling of glass cartridges are revealed. An examination of the growing healthcare cost curve and how device technology can make an impact in producing measurable patient outcomes is featured. Questions that focus on complex packaging challenges and how to achieve optimal market potential are addressed.



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MONDAY, OCTOBER 17, 2016 AGENDA (CONTINUED)

A1 – Key Ingredients of Effective Partnerships (continued)

1:30 p.m. – 2:00 p.m.

Collaborative Partnership between Device Manufacturers and Bio/Pharmaceutical Companies to Ensure Optimized Combination Products for Injectable Drugs

Tom McLean, Vice President, Delivery Systems, Research & Development, *West Pharmaceutical Services, Inc.*

Bill Rich, Vice President, Device Technologies, *Amgen Inc.*

2:00 p.m. – 2:30 p.m.

Three Months from Concept to Demo: Mobile Device Case Study

Andy Rogers, Director of Business Development, *KeyTech, Inc.*

2:30 p.m. – 3:00 p.m.

Questions and Answers/Discussion

B1 – Will Recent Advances in Secondary Packaging Help Meet the Challenges of Glass Breakage? (continued)

1:30 p.m. – 2:00 p.m.

Global Market Trends for Advanced Combination Products – How Innovations Can Contribute to Better Patient Outcomes

Mathias Romacker, Senior Director, Device Strategy, *Pfizer, Inc.*

2:00 p.m. – 2:30 p.m.

Case Study: Reduction of Glass Breakage in Pharmaceutical Process, a Systematic and Practical Approach

Mads Reedtz Espersen, Principal Specialist, Primary Packaging Development, *Novo Nordisk A/S*

2:30 p.m. – 3:00 p.m.

Questions and Answers/Discussion

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 – Connectivity: Data Collecting from Patient Behavior Moderator: Georg Roessling, PhD, Senior Vice President, PDA Europe

Session Description: It started with hardware to improve the convenience of the drug application. From vials or ampoules to pre-filled syringes and, as a next step, syringes or cartridges incorporated into human factor designed-devices, such as auto-injectors, pens and wearables, this session will give you insights into recent developments focusing on how electronics can be implemented in devices, making them “intelligent.” Electronics can help in describing the application procedure and collecting data on how the application was performed. The collected data can be assessed and then used, for example, to modify the application. Technical examples will be given and potentials for the future will be discussed.

B2 – Current Issues Regarding Silicone-Oil Induced Protein Aggregation: A Cause for Immunogenicity Effects? Moderator: Christian Helbig, Head of Global Business Development Syringes, SCHOTT Schweiz AG

Session Description: At a recent public European Medicines Agency workshop, the topic of immunogenicity caused by protein aggregates was discussed. This session addresses one aspect of this topic, the aggregation caused by silicon oil that is used as lubricant in syringes and cartridges. In-vitro data and clinical data will be presented to describe current knowledge in the field.

MONDAY, OCTOBER 17 – TUESDAY, OCTOBER 18, 2016 AGENDA

A2 – Connectivity: Data Collecting from Patient Behavior (continued)	B2 – Current Issues Regarding Silicone-Oil Induced Protein Aggregation: A Cause for Immunogenicity Effects? (continued)
<p>3:45 p.m. – 4:15 p.m. Hands-On Approach to Developing an Optimized Connected Drug Delivery Device System Hans Jensen, Senior Business Development Manager, <i>Medicom Innovation Partner</i></p> <p>4:15 p.m. – 4:45 p.m. Mobile Health and its Impact on Diabetes Management: How Health Data in the Cloud Contributes to Better Health Outcomes? Marcus Hompesch, MD, Chairman & Chief Executive Officer, <i>Profil Institute for Clinical Research, Inc.</i></p> <p>4:45 p.m. – 5:15 p.m. Questions and Answers/Discussion</p>	<p>3:45 p.m. – 4:15 p.m. Silicone-Oil Induced Protein Aggregation and Immunogenicity John Carpenter, PhD, Professor of Pharmaceutical Sciences, School of Pharmacy, <i>University of Colorado</i></p> <p>4:15 p.m. – 4:45 p.m. Silicone-Oil Induced Protein Aggregation: A Cause for Immunogenicity Effects? John Ayres, MD, Health Hazard Evaluation Physician, <i>Eli Lilly & Company</i></p> <p>4:45 p.m. – 5:15 p.m. Questions and Answers/Discussion</p>

7:00 p.m. – 10:00 p.m.

Seaside Social

Tuesday, October 18, 2016

7:00 a.m. – 8:30 a.m.

Continental Breakfast

7:00 a.m. – 5:30 p.m.

Registration Open

7:15 a.m. – 8:15 a.m.

Breakfast Sessions

8:30 a.m. – 10:00 a.m.

P3 – Global Regulations and Standards Related to Pre-filled Syringes and Injector Devices

Moderator: Kathy Lee, Senior Regulatory Advisor, *Eli Lilly & Company*

Session Description: The regulatory landscape for pre-filled syringes and injector devices is complex. The U.S. FDA regulates pre-filled syringes and injector devices as combination products where two quality systems must align. For legacy products, this can be very challenging. What information should be updated or created to meet regulatory expectations? Where should this information reside and how should it be provided and when? This session will focus on talks from the U.S. FDA and a case study to help shed light on these important questions.

8:30 a.m. – 9:00 a.m.

Regulatory Perspectives on Healthcare Technologies

Regulatory Representative (Invited)



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TUESDAY, OCTOBER 18, 2016 AGENDA (CONTINUED)

P3 – Global Regulations and Standards Related to Pre-filled Syringes and Injector Devices *(continued)*

9:00 a.m. – 9:30 a.m.

Bridging Design and Documentation: A Look into Design Control Strategy for a Legacy Vaccine

Anelyn Tolentino, Senior Manager, Process Development, *Pfizer, Inc.*

9:30 a.m. – 10:00 a.m.

Questions and Answers/Discussion

9:45 a.m. – 4:00 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 – Innovative Containment and Delivery Systems for Today's Challenging Biologics

Moderator: Shawn Kinney, PhD, Chief Executive Officer, *Berkshire Sterile Manufacturing*

Session Description: With the advent of more sophisticated and challenging biologic drugs, the selection of appropriate containment systems becomes more critical. This session will explore innovations in the area of pre-filled syringe systems, focusing on the elimination of silicone oil and the transition toward polymer container systems for enhanced performance.

10:45 a.m. – 11:15 a.m.

Silicone-Free Pre-filled Syringes: From Feasibility to Reality

Jeffrey M. Brake, PhD, New Product Development Associate, *W.L. Gore & Associates, Inc.*

Nicolas Eon, PhD, Product Manager, Glass Syringes, *SCHOTT Pharmaceutical Packaging*

11:15 a.m. – 11:45 a.m.

Polymer Container Systems – Perspective from Biopharma Drug and Container Manufacturers

Ronald Forster, PhD, Executive Director, Device & Final Drug Product Technologies, *Amgen, Inc.*

Scott Young, PhD, Vice President, Container Systems, *West Pharmaceutical Services, Inc.*

B3 – International Regulatory Pathways for Auto-injectors and Pens

Moderator: Joel Cotten, Business Development Director, *Aptar Pharma*

Session Description: As we know, combination products are comprised of any combination of a drug and a device. This said, combination products remain subject to the regulatory requirements associated with their constituent parts. As a number of pharmaceutical companies have, in different parts of the world, successfully launched several similar combinations products embedding a pre-filled syringe, we assume that an original regulatory strategy will support all these successes.

10:45 a.m. – 11:15 a.m.

Success in a Global Launch of Combination Products

Manfred Maeder, PhD, Head GCA, Devices & Combination Products, *Novartis Pharma AG*

11:15 a.m. – 11:45 a.m.

Differences and Similarities between Europe and U.S. Registration Strategies

Mark Chipperfield, Principal Consultant & Company Director, *Corvus Device Limited*

TUESDAY, OCTOBER 18, 2016 AGENDA (CONTINUED)**A3 – Innovative Containment and Delivery Systems for Today's Challenging Biologics** *(continued)*

11:45 a.m. – 12:15 p.m.

Questions and Answers/Discussion**B3 – International Regulatory Pathways for Auto-injectors and Pens** *(continued)*

11:45 a.m. – 12:15 p.m.

Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.

Networking Lunch in Exhibit Hall (Sponsored in part by *Owen Mumford*)

1:45 p.m. – 3:15 p.m.

Concurrent Sessions**A4 – Manufacturing Equipment Innovation****Moderator: Olivia Henderson, PhD**, Principal Engineer, *Amgen, Inc.*

Session Description: Innovation is the watchword recently, but it doesn't stop with cell phone apps, new materials of construction or new ways of collecting and interpreting data. Innovation may also refer to new or more efficient manufacturing modalities. This session will present new manufacturing technology and innovative ideas that can increase efficiency and reliability, thereby enabling patients to maintain full accessibility to innovative medications.

1:45 p.m. – 2:15 p.m.

Innovative Sterile Manufacturing System for Multiple Primary Container Types, Sizes and Presentations**Shawn Kinney, PhD**, Chief Executive Officer, *Berkshire Sterile Manufacturing*

2:15 p.m. – 2:45 p.m.

Drug Product Cutting-Edge Technologies and How Cutting-Edge Technologies Can Reduce Regulator Risk and Reduce the Validation Burden**Sean Goudy, PhD**, Associate Director, *Biogen*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion**B4 – Primary Container Innovation****Moderator: William Dierick**, Director, Technology Development, *Terumo Europe N.V.*

Session Description: Over the past decades, parenteral drug development has been driven by the rapid growth of therapeutic protein development, now one of the main technology developments of the 21st century. The production of biological drugs is a complex and inherently unstable situation, requiring special handling and storage. Therefore, there are important interrelated areas in the development of these drugs with the primary drug container system. This session will inform the audience about the progress of innovation related to primary drug containers in support of improving drug efficacy and patient safety.

1:45 p.m. – 2:15 p.m.

Extractables Study on COP Polymer Pre-filled Syringes Having a Focus on Biotherapeutics**Kevin Constable**, Senior Director of Technology Development, *Terumo Medical Corporation*
Piet Christiaens, PhD, Scientific Director, *Toxikon*

2:15 p.m. – 2:45 p.m.

Next Generation Lubricant Technology for Parenteral Syringes and Cartridges**Christopher Weikart, PhD**, Director, Research & Development *SiO2 Medical Products*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion

3:15 p.m. – 4:00 p.m.

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



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TUESDAY, OCTOBER 18, 2016 AGENDA (CONTINUED)

4:00 p.m. – 5:30 p.m.

P4 – Global Market Trends

Moderator: Wenzel Novak, PhD, Director, Pharmaceutical R&D, *Groninger & Company GmbH*

Session Description: Globalization covers significantly more different requests by indication, regulatory and technical aspects on the same product. During all phases, clinical studies have to consider worldwide aspects and differences. Two case studies will reflect the effective response to the global market needs.

4:00 p.m. – 4:30 p.m.

Placebo Challenges in a Clinical Study Using an Auto-injector: What are the Considerations and How Do You Pick the Right Placebo Formulation?

Horst Koller, Chief Executive Officer, *HK Packaging Consulting GmbH*

Oliver Kooistra, PhD, Project Manager, *medac GmbH*

4:30 p.m. – 5:00 p.m.

Changing Regulations and Global Challenges in Emerging Countries

Industry Representative (*Invited*)

5:00 p.m. – 5:30 p.m.

Questions and Answers/Discussion

5:30 p.m.

Closing Remarks and Adjournment

Olivia Henderson, PhD, Principal Engineer, *Amgen, Inc.*, and Chair, 2016 PDA Universe of Pre-filled Syringes & Injection Devices Program Planning Committee

2016 PDA Universe of Pre-filled Syringes & Injection Devices Exhibition and Sponsorship Packages Available!

The 2016 PDA Universe of Pre-filled Syringes & Injection Devices will provide your company with exclusive exhibit and sponsorship opportunities to gain access to and network with hundreds of key decision makers from the biopharmaceutical science and manufacturing industry. Become a sponsor and/or exhibit at this industry-leading event to connect with industry thought leaders, showcase new products and services, strengthen your brand image, increase your visibility, grow your business and show your company's strong commitment to the industry. This is a must-attend event for all industry professionals involved in the development, manufacturing or use of pre-filled syringes and injection devices.

For exhibit and/or sponsorship information, please contact:



David Hall

Vice President, Sales

Direct: +1 (301) 760-7373

Cell: +1 (240) 688-4405

Email: hall@pda.org



2016 PDA UNIVERSE OF PRE-FILLED SYRINGES & INJECTION DEVICES COURSE SERIES – OCTOBER 20-21, 2016

PDA Education will be offering three courses designed to complement what you've learned at the Conference from October 20-21 at the Hyatt Regency Huntington Beach Resort and Spa in Huntington Beach, CA.

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 mail 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 Professional Engineers

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

PDA is recognized by the North Carolina Board of Examiners for Engineers and Surveyors as an Approved Sponsor of 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. Continental breakfast will be served before class beginning at 7:30 a.m. Lunch will be provided from 12:00 p.m. – 1:00 p.m. Snacks will be provided during the morning break from 10:00 a.m. – 10:15 a.m. and the afternoon break from 2:30 p.m. – 2:45 p.m.

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



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2016 PDA UNIVERSE OF PRE-FILLED SYRINGES & INJECTION DEVICES COURSE SERIES – OCTOBER 20-21, 2016 (CONTINUED)

Understanding and Addressing Technical, Quality and Regulatory Challenges for Drug Delivery Combination Products **NEW COURSE**

Location: Hyatt Regency Huntington Beach Resort and Spa | Huntington Beach, CA

Date: October 20, 2016

Duration: 1 day

Time: 8:30 a.m. – 4:00 p.m.

PDA #511 | ACPE #0116-0000-15-021-L04-P | 0.6 CEUs

Type of Activity: *Knowledge*

This course will have interactive discussions of the challenges companies will face in the development and registration of drug delivery combination products.

Topics will include:

- Applicable regulatory schemes in the U.S. and EU and some potential regulatory strategies
- Impact and expectations for GMP/QSR compliance
- Technical requirements—creation of a design history file
- Current clinical requirements
- Expectations and challenges
- Partner (vendor) selection and oversight and format
- Elements and data requirements for marketing authorization submissions

Who Should Attend

This course will be geared toward individuals that have input into, oversight for or actively participate on drug delivery combination product development teams.

This includes the following practitioners, managers and directors in medical device, pharmaceutical or consulting companies:

Project management | Marketing | Regulatory Affairs | Quality Assurance | Clinical Affairs | Human Factors Engineering | Device Development Engineering | Quality Engineering | Formulation | Testing Laboratories | Design Verification Department

Learning Objectives

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

- Explain the basic elements and requirements behind the regulation of drug delivery combination products
- Plan, 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 a robust risk management and human factors engineering systems and, if qualified, 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, RAC, MBA, President, *P/L Biomedical*

Understanding Product Options, User Needs and Fill-Finish Requirements for Nested Format Syringes, Cartridge Containers and Drug Delivery Systems **NEW COURSE**

Location: Hyatt Regency Huntington Beach Resort and Spa | Huntington Beach, CA

Date: October 20, 2016

Duration: 1 day

Time: 8:30 a.m. – 4:00 p.m.

PDA #351 | ACPE # 0116-0000-16-017-L04-P | 0.6 CEUs

Type of Activity: *Knowledge*

If you are developing a drug intended for pre-filled applications, the component design and material selection during development must take into account intended user requirements and fill/finish requirements. This one-day course will focus on providing a detailed understanding of the newest packaging technologies that support evolving drug and patient needs, considerations that must take into account quality expectations to fulfill regulatory requirements and how new manufacturing strategies are being applied to provide flexibility and decreased investments. The course will follow a practical approach to assist you in understanding the influences of all involved components and processes such as glass, polymer, elastomer, bulk, nested, silicon, filling and closing. The instructors will give a detailed insight of the complex interaction between components, containers and processes. There will also be discussions on how to avoid issues in development and overcome hurdles faster.

2016 PDA UNIVERSE OF PRE-FILLED SYRINGES & INJECTION DEVICES COURSE SERIES – OCTOBER 20-21, 2016 (CONTINUED)

Who Should Attend

This course is for drug development scientists, packaging and conditioner development engineers and device engineers as well as 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 the 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, PhD, Director, Pharmaceutical R&D,
Groninger & Company GmbH

Tibor Hlobik, Sr. Director Product Management Prefilled Systems
& Delivery, *West Pharmaceutical Systems, Inc.*

Alessandro Morandotti, Product Manager, *Nuovo Ompi*

Essential Elements of Extractables and Leachables: From Material Selection to Final Report

Location: Hyatt Regency Huntington Beach Resort and Spa |
Huntington Beach, CA

Date: October 21, 2016

Duration: 1 day

Time: 8:30 a.m. - 4:00 p.m.

PDA #252 | ACPE #0116-0000-15-020-L04-P | 0.6 CEUs

Type of Activity: Knowledge

This lecture and discussion based course will demonstrate, through examples and case studies, the essential elements of the extractables and leachables (E&L) process, from the selection and evaluation of packaging materials to the writing of the study report (conversion of data to information). E&L from both packaging and processing materials will be discussed with emphasis on small and large volume injectable drug products. The application of important concepts such as the safety concern threshold, qualification threshold and analytical evaluation threshold will be demonstrated with small volume parenterals/large volume parenterals examples. Current best practices, particularly those presented by PQRI, for the toxicological and safety qualification of E&L will be reviewed. Finally, a review of regulators' expectations with regard to common E&L study practices will be shared.

Who Should Attend

Professionals associated with drug and device companies, testing laboratories, consulting enterprises, and packaging/processing materials developers, standards development and regulatory agencies will benefit from this course.

This includes those working in the areas of:

Packaging/Package Engineering | Drug Formulation | Analytical Chemistry | Pharmaceutical Science | Quality Systems and Control | Regulatory Affairs | Materials Development | Consultants – Packaging and Process

Learning Objectives

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

- Evaluate and select packaging components/materials in order to mitigate safety and quality concerns
- Describe and be able to use the safety concern threshold, qualification threshold and analytical evaluation threshold concepts to plan and evaluate data from E&L studies (data vs. information)
- Explain the safety and toxicological issues that impact the analytical testing challenges
- Discuss both the published regulatory documents and current regulators expectations regarding E&L practices

Faculty

Edward J. Smith, PhD, Principal Consultant,
Packaging Science Resources, LLC

Diane Paskiet, Associate Director, Scientific Affairs,
West Pharmaceutical Services, Inc.

2016 PDA Universe of Pre-filled Syringes & Injection Devices (October 17-18) and 2016 PDA Drug Delivery Combination Products Workshop (October 19)

Hyatt Regency Huntington Beach Resort and Spa | Huntington, CA
Exhibition: October 17-18 | Workshop: October 19 | Courses: October 20-21

Four easy ways to register –

Click: pda.org/2016prefilled

Fax: +1 (301) 986-1093 (USA)

Mail: PDA Global Headquarters
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA

Call: +1 (301) 656-5900 ext 115



1 Contact Information PDA Membership Number:

Prefix	First Name	Last Name
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Country	Email	
Business Phone	Fax	

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

☐ Substituting for

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

Register for both the Conference and Workshop to receive an additional \$95 in savings.

2 CONFERENCE Registration | October 17-18, 2016

Please check appropriate fee (US\$).

	Before Aug. 5, 2016	Aug. 5 – Sept. 2, 2016	After Sept. 2, 2016
PDA Member	<input type="radio"/> \$ 1,995	<input type="radio"/> \$ 2,395	<input type="radio"/> \$ 2,595
Nonmember	<input type="radio"/> \$ 2,254	<input type="radio"/> \$ 2,654	<input type="radio"/> \$ 2,854
Government/Health Authority Member	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700
Nonmember*	<input type="radio"/> \$ 800	<input type="radio"/> \$ 800	<input type="radio"/> \$ 800
Academic Member	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700
Nonmember*	<input type="radio"/> \$ 800	<input type="radio"/> \$ 800	<input type="radio"/> \$ 800
Student Member	<input type="radio"/> \$ 280	<input type="radio"/> \$ 280	<input type="radio"/> \$ 280
Nonmember*	<input type="radio"/> \$ 310	<input type="radio"/> \$ 310	<input type="radio"/> \$ 310

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

3 WORKSHOP Registration | October 19, 2016

Please check appropriate fee (US\$).

2016 PDA Drug Delivery Combination Products Workshop Workshop Only	<input type="radio"/> \$ 800
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6 Payment Options All cards are charged in US\$.

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

Total amount \$ _____

Account Number _____

Name (exactly as it appears on card) _____

Billing Address (Billing address must match credit card statement) _____

City _____

State _____

Zip _____

PDA Federal Tax I.D. #52-1906152

Country _____

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

Please bill my: ☐ American Express ☐ MasterCard ☐ VISA

☐ Credit Card Guarantee Only

Exp. Date _____

Signature _____

Special Dietary Requirements (Please be specific): _____

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

4 NETWORKING Registration Please check appropriate fee (US\$).

Sunday, October 16, 2016 Walk/Run Event	# of tickets: _____	<input type="radio"/> \$45 per registered attendee or guest.
Monday, October 17, 2016 Seaside Social	# of tickets: _____	<input type="radio"/> \$60 per guest. All full conference attendees are welcome to attend.
Total Due		\$ _____

5 COURSE Registration | October 20-21, 2016

Please check appropriate fee (US\$).

PDA #511 Understanding and Addressing Technical, Quality and Regulatory Challenges for Drug Delivery Combination Products (October 20)

PDA #351 Understanding Product Options, User Needs and Fill-Finish Requirements for Nested Format Syringes, Cartridge Containers and Drug Delivery Systems (October 20)

PDA #252 Essential Elements of Extractables and Leachables: From Material Selection to Final Report (October 21)

		Course #511	Course #351	Course #252
Before September 2, 2016				
Standard	Member	<input type="radio"/> \$ 985	<input type="radio"/> \$ 985	<input type="radio"/> \$ 985
	Nonmember	<input type="radio"/> \$ 1,255	<input type="radio"/> \$ 1,255	<input type="radio"/> \$ 1,255
Government/Health Authority/Academic	Member	<input type="radio"/> \$ 600	<input type="radio"/> \$ 600	<input type="radio"/> \$ 600
	Nonmember*	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700
After September 2, 2016				
Standard	Member	<input type="radio"/> \$ 1,095	<input type="radio"/> \$ 1,095	<input type="radio"/> \$ 1,095
	Nonmember	<input type="radio"/> \$ 1,395	<input type="radio"/> \$ 1,395	<input type="radio"/> \$ 1,395
Government/Health Authority/Academic	Member	<input type="radio"/> \$ 600	<input type="radio"/> \$ 600	<input type="radio"/> \$ 600
	Nonmember*	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700	<input type="radio"/> \$ 700

Have a Campaign Code? Print Here:

CONFIRMATION: A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice, please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancellation notice is not received by **August 18, 2016**, your credit card will be charged the prevailing rate. **SUBSTITUTIONS:** If you are unable to attend, substitutions can be made at any time, including on-site at the prevailing rate. If you are 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:** Refund requests must be in writing and faxed to +1 (301) 986-1093. (Emails and phone messages are not accepted). **Refunds for Events:** If your written request is received on or before **August 18, 2016**, you will receive a full refund minus a \$200 processing fee. After that time, no refunds or credit requests will be approved. On-site registrants are not guaranteed to receive Conference materials until all advanced registered attendees receive them. PDA reserves the right to modify the material or speakers/instructors without notice or to cancel an event. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at info@pda.org or +1 (301) 656-5900. **PLEASE NOTE THAT PHOTO ID WILL BE REQUIRED IN ORDER TO PICK UP BADGE MATERIALS ON-SITE.** **THIS IMPORTANT SECURITY PROCEDURE WILL PREVENT ANYONE OTHER THAN THE REGISTRANT FROM PICKING UP THEIR BADGES AND MATERIALS.** **REFUNDS FOR COURSES:** If your written request is received by **September 19, 2016**, you will receive a full refund minus a \$200 processing fee. After that time, no refunds will be approved. **COURSE CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA 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/PHOTO RELEASE:** By registering for these events, I authorize PDA to record and photograph me and to use the recordings/photographs in all formats and media for any purpose, including for education, marketing and trade purposes. I hereby release PDA from all claims arising out of the use of the recordings/photographs, including without limitation all claims for compensation, libel, invasion of privacy or violation of copyright ownership. Tape recordings are prohibited at all PDA conferences.

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101716B

The Parenteral Drug Association presents the...

2016 PDA Drug Delivery Combination Products Workshop

*Addressing key challenges in development, approval and manufacture
of drug delivery combination products*

October 19, 2016 | Huntington Beach, CA
Hyatt Regency Huntington Beach Resort and Spa

Exhibition: October 19



Workshop Theme: Providing Approaches
and Solutions to Help Navigate the Evolving
Combination Product Environment

pda.org/2016combo
#2016combo

This preliminary agenda is current as of May 16, 2016

RECORDINGS ARE PROHIBITED AT ALL PDA EVENTS



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PROGRAM PLANNING COMMITTEE

Program Chair

Lee Leichter, RAC, MBA
P/L Biomedical

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Eli Lilly & Company

Manfred Maeder, PhD
Novartis Pharma AG

Diane Paskiet
West Pharmaceutical Services, Inc.

Alberto Velez
Johnson & Johnson

Jason Brown
PDA Liaison to the Program Planning Committee

Josh Eaton, PMP
PDA Scientific and Regulatory Affairs Liaison

A MESSAGE FROM THE PROGRAM CHAIR



Lee Leichter, RAC, MBA
P/L Biomedical

You are invited to attend the 2016 PDA Drug Delivery Combination Products Workshop that directly follows the 2016 PDA Universe of Prefilled Syringes and Injection Devices in Huntington Beach this October.

This one-day Workshop will provide advice from prominent experts in this field, real-life experiences from leading bio/pharmaceutical companies and updates and recommendations from the U.S. FDA. There will also be opportunities to interact with, and listen to, experts through panel discussions. At this Workshop, you will learn about the challenges that your company may face and benefit from the lessons companies have

learned from their experiences and understand the U.S. FDA's expectations regarding drug delivery combination products.

The Workshop will cover many of the ongoing and future challenges the industry is facing, including human factors, where in the U.S., FDA recently recognized that combination products have unique issues and detailed its current thinking in a draft guidance. Other key areas include clinical studies, risk management and, as more combination products are transferred to manufacturing and are commercialized, the new challenges of design transfer, change controls and FDA inspection compliance expectations.

Sessions will cover key issues in this important area. Topics include human factors/risk management, which will focus on appropriate user research, characterizing users' needs and good human factors engineering, all of which are integral parts of the design and development of patient-centric drug delivery systems. Design verification testing, critical quality attributes, release and stability testing will look at how organizations integrate critical-to-quality attributes and stability testing into the design verification process.

The session on Design/Technology Transfer will identify challenges posed by technology transfer and design transfer and methods that have been successfully implemented to address both of these issues. GMPs, inspections and change management will cover industry approaches to design changes and the U.S. FDA's approaches to inspection for drug delivery combination products.

Clinical studies/level of design controls phase I, II and III will address the types of clinical studies that are requested and can be performed to support NDA/BLA, ANDA and biosimilar drug delivery combination product submissions and the level of design controls necessary to be completed for type/phase of study. Future solutions to the patient experience/challenges with drug delivery devices will focus on how technology and human factors can be used to promote a superior patient experience.

We hope that you will join us and participate in the exciting Workshop addressing the most current and important issues related to combination products.

GENERAL INFORMATION, REGISTRATION

Four Ways to Register

- 1. Click** pda.org/2016combo
- 2. Fax** +1 (301) 986-1093
- 3. Mail** PDA Global Headquarters
Bethesda Towers
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA
- 4. Phone** (301) 656-5900 ext. 115

Venue

Hyatt Regency Huntington Beach Resort and Spa

21500 Pacific Coast Highway
Huntington Beach, CA 92648

Phone: +1 (714) 698-1234

Website: www.huntingtonbeach.hyatt.com

Rate: Single: \$269 plus applicable state and local taxes.

Cut-Off Date: Thursday, September 15, 2016

(Availability may be limited. Requests will be processed on a first-come, first-served basis. Attendees staying within the PDA block will receive the Workshop rate.)

Continuing Education Credits



PDA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants may sign up to receive Continuing Pharmacy Education (CPE) credits.

To do so, participants must sign in at the beginning of the program, submit the provided evaluation forms and mail the CPE credit request to the address stated on the form. Attendees must be present at the full event to receive CPE credit, which will be awarded as follows:

2016 PDA Drug Delivery Combination Products Workshop

ACPE # 0116-0000-16-013-L04-P | 0.6 CEUs

Type of Activity: *Knowledge*

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.

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 organizations 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

Departments

Device Development | Compliance | Operations | Regulatory Affairs | Manufacturing | Pharmaceutical Formulation and Process Development | Business Development | Marketing | Procurement | CMC | Distribution | Packaging | Quality Assurance/Control | Clinical Affairs

Job Function

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

Workshop Registration Hours

Wednesday, October 19: 7:15 a.m. – 5:15 p.m.

Dress/Attire

Business casual attire is recommended for the 2016 PDA Drug Delivery Combination Products Workshop. 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

Workshop Inquiries

Jason Brown

Manager, Programs &
Registration Services
Tel: +1 (301) 656-5900 ext. 131
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Exhibition/Sponsorship Inquiries

David Hall

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WEDNESDAY, OCTOBER 19, 2016 AGENDA

7:15 a.m. – 8:15 a.m.

Continental Breakfast

7:15 a.m. – 3:45 p.m.

Exhibit Area Open

7:15 a.m. – 5:15 p.m.

Registration Open

8:15 a.m. – 8:30 a.m.

Welcome and Opening Remarks

Lee Leichter, RAC, MBA, President, *P/L Biomedical*, and Chair, 2016 PDA Drug Delivery Combination Products Workshop Program Planning Committee

8:30 a.m. – 10:00 a.m.

P1 – Human Factors/Risk Management

Moderator: Diane Paskiet, Associate Director, Scientific Affairs, *West Pharmaceutical Services, Inc.*

Session Description: The regulatory framework for combination products continues to progress with an emphasis on patient-centric drug delivery. The requirements of drug products and the beliefs and preferences of both the prescriber and the patient will influence choices of drug delivery options. It is essential for pharmaceutical companies to understand the patient's interaction with the delivery system in order to incorporate features that promote adherence to treatments. This session will focus on appropriate user research, characterizing users' needs and good human factors engineering, all of which are integral parts of the design and development of patient-centric drug delivery systems.

8:30 a.m. – 9:00 a.m.

A Human Factors Road Map for Self-Injection Device Design

Chris Evans, Vice President, Global Innovation, *West Pharmaceutical Services, Inc.*

9:00 a.m. – 9:30 a.m.

Risk-Based Approaches to Design and Development of Drug Delivery Systems

Molly Story, PhD, Head, Global Usability Engineering & Risk Management, *Sanofi*

9:30 a.m. – 10:00 a.m.

Questions and Answers/Discussion

Panelists:

Chris Evans, Vice President of Innovation, *West Pharmaceutical Services, Inc.*

Molly Story, PhD, Head, Global Usability Engineering & Risk Management, *Sanofi*
Regulatory Representative (*Invited*)

10:00 a.m. – 10:45 a.m.

Refreshment Break in Exhibit Area

10:45 a.m. – 12:15 p.m.

Concurrent Sessions

A1 – Design Verification Testing, Critical Quality Attributes, Release and Stability Testing

Moderator: Alberto Velez, Senior Director, Operations Readiness, *Johnson & Johnson*

Session Description: As design control in combination products begins to mature, we are beginning to improve how organizations are integrating critical-to-quality attributes and stability testing into the design verification process. This session will share current thinking on design verification, critical-to-quality attributes and stability testing of combination products are best approached.

B1 – Design/Technology Transfer

Moderator: Lee Leichter, RAC, MBA, President, *P/L Biomedical*

Session Description: Combination products add another layer to technology transfer for drug products. In addition to standard technology transfer, the sponsor must also address design transfer of the combination products. This session will identify these challenges and methods that have been successfully implemented to address them.

WEDNESDAY, OCTOBER 19, 2016 AGENDA (CONTINUED)

A1 – Design Verification Testing, Critical Quality Attributes, Release and Stability Testing <i>(continued)</i>	B1 – Design/Technology Transfer <i>(continued)</i>
<p>10:45 a.m. – 11:15 a.m. How a Center of Excellence Can Better Address Design Verification Susan Needle, Senior Director, Design-To-Value & PQM, <i>Janssen</i></p> <p>11:15 a.m. – 11:45 a.m. Integration of Essential Performance into Combination Product Control Strategies Suzette Roan, Associate Director, Regulatory Affairs, CMC Combination Products, <i>Biogen</i></p> <p>11:45 a.m. – 12:15 p.m. Questions and Answers/Discussion</p>	<p>10:45 a.m. – 11:15 a.m. Technology Transfer Mark Chipperfield, Principal Consultant & Company Director, <i>Corvus Device Limited</i></p> <p>11:15 a.m. – 11:45 a.m. Design Transfer Amit Khanolkar, Director, Combination Products & Emerging Technology, PQM, <i>Janssen</i></p> <p>11:45 a.m. – 12:15 p.m. Questions and Answers/Discussion</p>
<p>12:15 p.m. – 1:30 p.m. Lunch</p> <p>1:30 p.m. – 3:00 p.m. Concurrent Sessions</p>	
A2 – Clinical Studies/Level of Design Controls Phase I, II and III Moderator: Lee Leichter, RAC, MBA, President, P/L Biomedical	B2 – GMPs, Inspections and Change Management Moderator: Manfred Maeder, PhD, Head GCA, Devices & Combination Products, Novartis Pharma AG
<p>Session Description: This session will address the types of clinical studies that are requested and can be performed to support NDA/BLA, ANDA and biosimilar drug delivery combination product submissions and the level of design controls necessary to be completed for type/phase of study.</p>	<p>Session Description: The regulatory framework for combination products is rapidly developing with regular updates to guidelines and increased expectations. The requirements for appropriate change management pose challenges, because it is beyond the traditional pharmaceutical change control systems. Changes now need to consider updates to the design history file.</p>
<p>1:30 p.m. – 2:00 p.m. Device-Centric Studies for Combination Product Approval Doug Mead, Senior Director, Regulatory Affairs, <i>Janssen</i></p> <p>2:00 p.m. – 2:30 p.m. Design Verifications and Validations Required for Clinical Supplies Nicholas Wong, Senior Associate III, <i>Biogen</i></p> <p>2:30 p.m. – 3:00 p.m. Questions and Answers/Discussion</p>	<p>1:30 p.m. – 2:00 p.m. Change Management Practices and Post-Market Considerations Paul Jansen, Vice President, Medical Device Development, <i>Sanofi Pasteur</i></p> <p>2:00 p.m. – 2:45 p.m. Current Challenges during Combination Product Inspections Regulatory Representative <i>(Invited)</i></p> <p>2:45 p.m. – 3:00 p.m. Questions and Answers/Discussion</p>
<p>3:00 p.m. – 3:45 p.m. Refreshment Break in Exhibit Area</p>	



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WEDNESDAY, OCTOBER 19, 2016 AGENDA (CONTINUED)

3:45 p.m. – 5:15 p.m.

P2 – Future Solutions to the Patient Experience/Challenges with Drug Delivery Devices

Moderator: Ronald Iacocca, PhD, Research Fellow, Delivery/Device R&D, *Eli Lilly & Company*

Session Description: Combination products have to consider numerous factors in addition to the efficacy of the treatment. As many of the diseases treated by combination products are chronic, the patient experience must be positive so that the treatment will be used. Technology and human factor considerations are crucial to the success of the therapy. Technology, through things such as connected solutions, can provide greater information to healthcare providers to enable better patient care and outcomes. Human factors help to ensure that devices are easy to use, safe and reliable. This session will focus on how technology and human factors can be used to promote a superior patient experience.

3:45 p.m. – 4:15 p.m.

Innovation and Emerging/New Technologies for Parenteral Delivery

Marie Schiller, Vice President, Innovation, *Eli Lilly & Company*

4:15 p.m. – 4:45 p.m.

Human Factors and Consideration for Integration of Connected Health to Devices

Tyler Blake, PhD, Chief Scientist, *Human Factors Consulting Services, Inc.*

4:45 p.m. – 5:15 p.m.

Questions and Answers/Discussion

5:15 p.m.

Closing Remarks and Adjournment

Lee Leichter, RAC, MBA, President, *P/L Biomedical*, and Chair, 2016 PDA Drug Delivery Combination Products Workshop Program Planning Committee

2016 PDA Drug Delivery Combinations Products Workshop Exhibition and Sponsorship Packages Available!

The 2016 PDA Drug Delivery Combination Products Workshop will provide your company with a premier opportunity to network with key decision makers in this dynamic field. Find new customers and strengthen current relationships by exhibiting at and/or sponsoring this Workshop.

The Workshop agenda will provide ample opportunity for exhibitors to have face-to-face dialogue and direct information exchange with industry professionals who are involved in development, approval and manufacturing of drug delivery combination products. Company representatives will be on hand from compliance, CMC, packaging, operations, quality, regulatory affairs, supply chain, procurement and other technical functions.

Become a sponsor and/or exhibit at the 2016 PDA Drug Delivery Combination Products Workshop to strengthen your brand image, increase your visibility and gain access to leaders and subject matter experts in the bio/pharmaceutical industry.



For more information, contact:

David Hall, Vice President, Sales

Direct: +1 (301) 760-7373 | Cell: +1 (240) 688-4405

Email: hall@pda.org