Sunday, October 5, 2014

8:00 a.m. - 10:30 a.m.
PDA California Fun Run – Supporting the CSP Huntington Beach Youth Shelter
Co-Sponsored by the PDA Southern California Chapter

1:00 p.m. - 5:30 p.m.
Pre-filled Syringe Technical Report Team Meeting (*Invitation only*)

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

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

5:00 p.m. - 6:00 p.m.
2014 PDA Universe of Prefilled Syringes and Injection Devices Program Planning Committee Meeting (*Committee members only*)

Monday, October 6, 2014

7:15 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
Adalberto Ramirez, Vice President, Quality, Amgen, Inc. and Chair, 2014 PDA Universe of Prefilled Syringes and Injection Devices Program Planning Committee

8:30 a.m. - 10:00 a.m.
P1 - Opening Plenary Session: Focus on Innovation
**Moderator: Adalberto Ramirez, Vice President, Quality, Amgen, Inc.**

The health care industry has made enormous progress in bringing new products to the market to improve patients’ quality of life. We are fortunate to see that innovation continues to flourish for the benefit of the patients. Despite all the challenges in the innovation process, the results are encouraging. We still need to improve in the administration, compliance, safety, costs and accuracy of dosing by taking integrated approaches to develop drug delivery systems that help improve patient’s quality of life. Aging populations, increased regulatory scrutiny, increased competition in global markets, cost pressures and protecting the supply chain are among the many challenges faced by our industry. New advances in materials of construction, automated manufacturing processes, injection processes, safety devices and technology improvements create a dynamic environment in the drug delivery device arena. You innovate or your business will face very difficult challenges.

In this session, we will share the reality of the industry through the Global Life Sciences report and will discuss the essential parts of innovation in combination products. The focus of these presentations is on the new developments that will help improve patient compliance and therefore improve their quality of life. We will share experiences, new developments, regulatory considerations, challenges and industry trends in this exciting area.

8:30 a.m. - 9:00 a.m.
Progressions: Pharma 3.0
Glen Giovannetti, Global Life Sciences Leader, Ernst & Young
*Sponsored by Unilife*
9:00 a.m. - 9:30 a.m.
**Essential Parts of Innovation in Combination Products: Improving Patient Outcomes**
Sheldon Moberg, Vice President - Drug Delivery, *Amgen, Inc.*

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

9:45 a.m. - 3:45 p.m.
**Exhibit Area Open**

10:00 a.m. - 10:45 a.m.
**Refreshment Break and Poster Presentations in Exhibit Area**

**Poster Presentation Listings**
( Presenters are available during the following breaks: 10:00 a.m. - 10:45 a.m. and 3:00 p.m. - 3:45 p.m.)
*Poster presenters will be available at their displays to answer questions during refreshment breaks*

- **50ml Device Evaluation:** Observation of 1270 Infusions with Syringe Pumps Validating Better Infusion Performance and Improved Safety for the Patient and the Healthcare Worker  
  Cecile Berteau, Clinical Development Manager, *BD Medical, Pharmaceutical Systems*

- **Human Factors Usability Testing on a New Hollow Microstructured Transdermal System (hMTS) Injector**  
  Allan Bohlke, PhD, hMTS Project Leader - MTS Technology and Product Development, *3M*

- **Technical Data update on Cyclic Olefin Polymer (COP)**  
  Brian Cail, Vice President - New Business Development, *Zeon Chemicals L.P.*

- **Safe Auto-Needles (SANs) Case Study:** Market Research Uncovering Patients’ Unmet Need and Usability Studies with Patients Using the SANs for this Unmet Need  
  David Daily, Chief Executive Officer, *DALI Medical Devices*

- **Factors Influencing the Selection and Development of Delivery Devices:** Can Device Features Help Reduce Patient Discomfort During Injection?  
  Mark Di Cioccio, Managing Consultant, *Team Consulting Ltd.*

- **Assessment of Acceptable Subcutaneous Injection Volumes and Flow Rates**  
  Diane Doughty, PhD, Scientist II - Drug Delivery & Devices, *MedImmune*

- **Image filtering techniques and impact of light level on Automated Inspection**  
  Massimo Frasson, General Manager, *Brevetti CEA*  
  Jean-Michael Tasserit, Référent Mirage Automatique, *Aspen*

- **Comparing HPLC and UPLC Methods for the Determination of Related Compounds in a Compendial Adrenaline Injection Product**  
  Brian Woodrow, PhD, Manager, Product Development, *Catalent Pharma Solutions*

- **Ethnographic Research for the Investigation of Compliance and Persistence Issues related to Various Treatment Indications**  
  Felix Jiang, Human Factors Engineer, *Genentech, Inc.*

- **Achieving Successful Medical Device Design by Early Material Selection**  
  Wim Vos, Application Development Engineer, *Celanese*

- **Sterilization Methods for Pre-fillable syringes (PFS) X-Ray Sterilization a More “Green” Alternative, Case Study: X-ray Sterilization for COC Polymer PFS**  
  Horst Koller, Head of Techical and Quality Support Syringes, *Schott Schweiz AG*

- **A Novel, Wearable Pre-Filled System for Large Volume Drug Delivery**  
  Peter Noymer, PhD, Executive Vice President of R&D and CTO, *SteadyMed Therapeutics*

- **Case Study: Precision Torque Monitoring & Precision Label Application for Pre-filled Syringe Assembly**  
  Alex Wardell, Director, *Kyoto America, Inc.*
**P2 - What's Hot in New Technologies & Devices? Are We Ready for Smart Phone Applications in the Industry?**  
**Moderator: Brigitte Reutter-Haerle, Director, Corporate Marketing, Vetter Pharma International**

This session offers attendees an opportunity to learn more about an exciting new PFS and microliter dosing technology system for the treatment of patients with age-related macular degeneration that offers significant advantages over conventional vials in regards to safety, efficacy, and compliance. A second presentation challenges attendees with thought provoking information, combined with supporting case studies, on the seemingly limitless use of smartphone apps with the potential to revolutionize our industry by improving patient safety and education, and improve upon the overall effectiveness of drug devices. Guidance on their use and current regulatory oversight is reviewed.

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<th>Time</th>
<th>Session</th>
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| 10:45 a.m. - 11:15 a.m. | **Drug Injections Into The Eye: Unmet Clinical & Compliance Needs, Opportunities for Novel Microliter Dosing PFS**  
**Anil Busimi, Head of Product Management - Syringe Business, Schott Schweiz AG**  
**Gautam Shetty, PhD, Director and General Manager, Advanced Drug Delivery Systems, Unilife** |
| 11:15 a.m. - 11:45 a.m. | **Connecting Drug Delivery Devices to Smartphone Applications and Mobile Medical Apps – Opportunities for Better Patient Compliance & Education or Regulatory Hurdle that Pharmaceutical Companies are Not Ready to Take?**  
**Markus Bauss, CEO, ConnectMeSmart GmbH** |
| 11:45 a.m. - 12:15 p.m. | Questions and Answers/Discussion |

12:15 p.m. - 1:30 p.m.  
**Networking Luncheon in Exhibit Area**

1:30 p.m. - 3:00 p.m.  
**Concurrent Sessions**

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<th>Time</th>
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| 1:30 p.m. - 3:00 p.m. | **A1 - Improving Patient Outcomes through Compliance and Adherence**  
**Moderator: David Haase, Senior Manager, Device Development, Genentech, Inc.**  
For a patient new to taking a drug that requires use of a device, the event can be intimidating or not totally understood. That can lead to a sub-optimal patient outcome. This session will focus on how to effectively get the patient started and trained in a way that gives them confidence in properly using their device. In addition we will look at innovative features designed into some devices that encourage better adherence to their dosing regimen. Together these approaches can help the patient be more adherent and achieve the full benefit that the combination product can offer. |
| 1:30 p.m. - 3:00 p.m. | **B1 - Trends and Challenges in Formulation & Development**  
**Moderator: Christina Braden-Moore, Director - Marketing, Pharmaceutical Systems, North America, Becton Dickinson**  
Successful commercialization of a product using a Contract Development and Manufacturing Organization (CDMO) requires a close partnership between the customer and the CDMO. In this session, the use of QbD principles for process development activities and challenges faced during technology transfer will be shared. A risk assessment based approach to evaluate the risk of specific unit operations on product quality will be discussed and an overall strategy for process validation including process review and robustness evaluation will be presented.  
Small volume, high concentration liquid formulations are required for certain indications such as rheumatoid arthritis, diabetes and other indications with strict drug product design considerations. The high concentrations present challenges for the manufacture, stability and delivery of the formulations. There is evidence to support that long term storage of high concentration liquid formulation of biologics in prefilled glass syringes or plastic syringes is potentially feasible. An evaluation of several drug product presentations of an IgG1 mAb at high concentrations will be discussed. Twenty four months of stability data on specifically, 140 mg/mL & 200 mg/mL of the mAb in two different buffers manufactured at small-scale and filled into glass syringes, polymer syringes, and glass vials will be presented. |
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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>1:30 p.m.</td>
<td>From Process Design to Continued Process Verification - A QbD Approach of Implementing a Syringe Product at a CDMO</td>
<td>Carolin Rether, PhD, Process Scientist, Process Development and Implementation, Vetter Pharma Fertigung GmbH &amp; Co KG</td>
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<td>2:00 p.m.</td>
<td>Evaluation of High Concentration Liquid Formulations (upto 200 mg/mL) of a Monoclonal Antibody in Glass and Plastic Syringes</td>
<td>Prashant Varma, Scientist, GlaxoSmithKline</td>
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<td>2:30 p.m.</td>
<td>Patient Adherence through Device Design</td>
<td>Bob Stabler, Senior Director of Business Development, Flextronics</td>
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<td>3:00 p.m.</td>
<td>Refreshment Break and Poster Presentations in Exhibit Area</td>
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<tr>
<td>3:45 p.m.</td>
<td>A2 - Improving Patient Outcomes through the Implementation of Human Factors</td>
<td>Sherri Biondi, Associate Director - Device Development, Genentech, Inc.</td>
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<td>3:45 p.m.</td>
<td>Aseptic Transfer Mechanisms and Processes of Pre-Sterilized Components Into an Isolator or RABS Syringe Fill Environment</td>
<td>Klaus Ullherr, Product Manager, Robert Bosch, GmbH Packaging Technology</td>
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<td>3:45 p.m.</td>
<td>B2 - Manufacturing Environment</td>
<td>Shawn Kinney, PhD, CEO, Berkshire Sterile Manufacturing</td>
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<tr>
<td>3:45 p.m.</td>
<td>Solutions for Flexible Fill/Finish Operations</td>
<td>Paolo Golfetto, Business Development Director, Ompi</td>
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### Concurrent Sessions

**A2 - Improving Patient Outcomes through the Implementation of Human Factors**

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

- Human factors are a critical input to the design process. More of our therapies are being designed to be delivered at home by the patient or the caregiver. Effectively designing these device systems to be patient friendly and robust is key to the delivery of the therapy being successful. This session will present key learnings and innovations in the field of patient experience. Through device design we can help the patient be more adherent and thus achieve the promised outcome from the medication.

- With the development of novel therapies, patients are requested to manage technical actions which were made in the past made by healthcare professionals (Injection, controls, reporting). Human factors considerations are key to ensure the success of these new therapies. This session will present key learnings or/and true new innovation in the field of the patient experience. The ultimate goal for the patient is to be as compliant as it is possible with respect to his disease.

**B2 - Manufacturing Environment**

**Moderator:** Shawn Kinney, PhD, CEO, Berkshire Sterile Manufacturing

- Parenteral drug products are often produced by sterile manufacturing processes when they cannot be terminally sterilized. Recent failures at some compounding pharmacies have brought increased attention to sterile manufacturing. Sterile manufacturing places extreme emphasis upon equipment, personnel, quality systems, procedures and practices to obtain the largest sterility assurance possible. The industry is developing technologies to improve the sterility assurance of sterile manufacturing and approach the sterility assurance of terminal sterilization methods. This session will consider new sterile manufacturing equipment, cleanroom/space design, rapid decontamination and transfer, and other technologies that promise to improve sterility assurance in sterile manufacturing and meet evolving regulatory requirements.

**Human Factors for Combination Product Development**

- Sherri Biondi, Associate Director - Device Development, Genentech, Inc.

**Human Factors Incorporated into Drug/Device Combination Products, an Auto-Injector Case Study**

- Evan Edwards, Vice President, Kaleo Pharma

**Aseptic Transfer Mechanisms and Processes of Pre-Sterilized Components Into an Isolator or RABS Syringe Fill Environment**

- Klaus Ullherr, Product Manager, Robert Bosch, GmbH Packaging Technology

**Solutions for Flexible Fill/Finish Operations**

- Paolo Golfetto, Business Development Director, Ompi
PDA's Surf-Side Beach Bash (Sponsored in part by Genentech)
You’re invited to ‘Hang-Ten’ or submerge yourself in some networking alongside the scenic Huntington Beach, California Lighthouse Courtyard. Come and enjoy this ‘chillax’ environment by wearing your best Tommy Bahama fashions and don’t forget to polish up those spiffy flip-flops to finish off your beach themed attire! Once here, you will enjoy your choice of popular coastal cuisines served ‘surfer-style’.
If you haven’t had enough, let the second wave crash over you while you dry off near the campfire and construct your own S’Mores, nibble on some fruit, or make a ‘rad’ Galaffle - a town favorite that will knock your flip-flops off! Take it all in while grooving to the sounds of the “Surf Tones”, a ‘stellar’ local band that will help you ‘dive right in’!

**Tuesday, October 7, 2014**

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

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

7:00 a.m. - 8:15 a.m.
Concurrent Breakfast Sessions

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>7:00 a.m. - 8:15 a.m.</td>
<td><strong>BR1 - Novel Plasma Coating Processes to Solve PFS Challenges</strong></td>
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<td>Moderator: Shawn Kinney, PhD, CEO, Berkshire Sterile Manufacturing</td>
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<tr>
<td>7:00 a.m. - 8:15 a.m.</td>
<td><strong>BR2 - Effective and Efficient Delivery of Parenterals: Injection Practice and Technology</strong></td>
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<td>Moderator: Richard Levy, PhD, Senior Vice President - Science &amp; Regulatory Affairs, PDA</td>
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<tr>
<td>7:00 a.m. - 8:15 a.m.</td>
<td><strong>BR3 – New Dual Chamber Injector Device and Improvement Procedures for Combination Products</strong></td>
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<td>Moderator: Georg Roessling, PhD, Senior Vice President, PDA Europe</td>
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This session will start with an overview of the current challenges that prefilled syringes face today, highlighting key characteristics of new plasma coating technologies to solve some of these. In the first presentation, a Parylene coating technology that offer solutions to existing interface incompatibilities and other performance related issues will be discussed. The second presentation, will investigate oxygen ingress rates for whole article PFS with detail on how each individual component within the systems plays a role in total ingress (plunger, needle shield, barrel). Comparisons will be shown for novel silicon oxide plasma coated COP, uncoated COP and glass syringe barrels. The data generated will provide a rationale to formulators and drug development programs to examine containers when faced with oxidation concerns.

There has been an increasing interest in optimizing the last stage of drug delivery using injection devices, the injection itself. Effective delivery of drug product into the patient as well as patient comfort and compliance are paramount. This session includes a clinical study completed to evaluate injection site leakage for SC injections as a function of volume, injection rate, and drug viscosity. This session will also highlight a new approach in needle manufacturing involving modifying and redefining the geometry of the cannula and needle point beveling. When combined with prefilled syringes and other injection devices, this new technology allows for injection of higher viscose formulations.

This session has two presentations. A new polymer based dual chamber autoinjector device is presented and a procedure describing criteria for assessing pen injector and autoinjector device changes. Such criteria are a necessity for continuous product improvement while being in compliance with regulatory requirements.
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<th>Time</th>
<th>Session</th>
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| 7:30 a.m. - 8:00 a.m. | A Systems Approach to Oxygen Permeation into a Pre-filled Syringe  
Christopher Weikart, PhD, Director of R&D, SiO2 Medical Products |
| 7:30 a.m. - 8:00 a.m. | Prefilled Syringes with Innovative Needle Technology Addressing Injectability Challenges and Patient’s Comfort  
Kevin Constable, Director Technology Development, Terumo |
| 7:30 a.m. - 8:00 a.m. | Injector Design Iterations to Promote Innovation  
John Towns, PhD, Principle Fellow, Eli Lilly & Company |

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<th>Time</th>
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| 8:30 a.m. - 10:00 a.m. | P3 - Global Regulations and Standards related to Prefilled Syringes and Injector Devices  
Moderator: Kathy Lee, Senior Regulatory Advisor, Eli Lilly & Company |

This session will address recent regulatory trends and developments in both US and EU markets for prefilled syringes and injector devices. Standards development in each region will also be covered.

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<th>Time</th>
<th>Session</th>
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| 8:30 a.m. - 9:00 a.m. | Challenges and Pitfalls for Applications Regarding Prefilled Syringes, Autoinjectors and Combination Products  
Lana Shiu, MD, Senior Medical Advisor - Office of Device Evaluation, CDRH, FDA |
| 9:00 a.m. - 10:00 a.m. | EU Regulations Panel Discussion  
Panelists:  
Ronald Forster, PhD, Executive Director - Packaging Design/Engineer, Amgen  
Kathleen O’Sullivan, Associate Director, Regulatory Affairs, BD Medical, Pharmaceutical Systems  
Rob Swift, Product Manager, Ompi of America - Stevanato Group |

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<th>Time</th>
<th>Session</th>
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<td>9:45 a.m. - 4:00 p.m.</td>
<td>Exhibit Area Open</td>
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<td>10:00 a.m. - 10:45 a.m.</td>
<td>Refreshment Break and Poster Presentations in Exhibit Area</td>
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**Poster Presentation Listing**  
(Presenters are available during the following breaks: 10:00 a.m. - 10:45 a.m. and 3:15 p.m. - 4:00 p.m.)  
*Poster presenters will be available at their displays to answer questions during refreshment breaks*

- **Getting it Right from the Start: Improving Drug-Container Instability Prediction with High Throughput Assays**  
Jean-Bernard Hamel, R&D Pharmaceutical Technology Senior Manager, BD Medical, Pharmaceutical Systems

- **Linking Component Selection to Drug Delivery Strategies in a Highly Competitive Market**  
Tibor Hlobik, Global Director - PFS Platform, West Pharmaceutical Services

- **Performance Benchmarking of New Cartridge Plungers and Cap Seals Coated with Fluoropolymers**  
Yen-Huei Lin, PhD, Principal Scientist, Teva Biopharmaceuticals

- **Traditional and Novel Sterilization Methods**  
Mason Schwartz, Operations Manager, Revox Sterilization Solutions

- **Evaluating Extractables and Leachables for Biologicals in Pre-Filled Syringes**  
James Scull, PhD, General Manager, NSF Health Sciences

- **Case Study - Experimental Evaluation of the Key Process Parameters (KPP) and their Impact on CQAs for the 1 mL Glass Syringe, on a Syringe Filler**  
Kiran Singh, Associate Director, Sandoz

- **Primary Packaging Enabling New Drug Product Development Paradigm**  
Peter Skufca, PhD, Technical Development Specialist and Inventor

- **Breaking the 1ml barrier: Overcoming Challenges and Delivering Solutions for Subcutaneous Injection**  
Hervé Soukiassian, Worldwide Cluster Leader, BD Medical, Pharmaceutical Systems
Biotech Formulations and Modern Blow-Fill-Seal processing - Still a Contradiction?
Michael Spallek, Director - Research & Development, Rommelag

Device Training: Case Study on the Effectiveness of Multisensory Smart Training Devices to Traditional Training Materials for Patients’ Onboarding to New Therapies
Paul Sullivan, Senior Business Development Manager, Noble

Comparing the Impact to Drug Product from a Silicon Oil Free Polymer Based Container when Compared to a Siliconized System
Mitsuru Takahashi, PhD, Assistant Manager of Technology Development, Terumo Medical Corporation

Multilayer Plastic Vial and Syringe Made of Oxygen Absorbing Layer
Kashiba Takashi, Team Leader, Mitsubishi Gas Chemical Company, Inc.

Comparison of Product Behavior During Lyophilization When Processed in Dual Chamber Cartridges and Tubing Vials
Michael Thomas, Senior Research Scientist, Lyophilization Technology, Inc.

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

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<th>10:45 a.m. - 12:15 p.m.</th>
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<tr>
<td><strong>A3 – Quality Aspects in Injectable Delivery Systems</strong></td>
<td><strong>B3 – New Manufacturing Technologies: Methods and Processes</strong></td>
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<tr>
<td>Moderator: Georg Roessling, PhD, Senior Vice President, PDA Europe</td>
<td>Moderator: Wenzel Novak, PhD, Director - Pharmaceutical R&amp;D, Groninger &amp; Company GmbH</td>
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Delivery systems have become more complicated over the past decade. To ensure a delivery system functions as intended quality must be designed into a delivery system from the concept phase. This section will focus on how quality systems are utilized in the design and development of delivery devices. It will also feature how quality systems are critical to monitoring device performance post commercialization.

Delivery systems are evolving and becoming more complicated and primary containers are no longer just simple vials and syringes. At the same time, parenteral container manufacturers are being expected to deliver higher quality, particle free, defect free and in many cases ready to fill containers. The industry is moving towards smaller batch sizes, customized medication and ready to fill primary containers. Rapid turnaround for a variety of sizes, containers, formats while maintaining high quality is required. This flexibility must, at the same time, not compromise the sterile manufacturing environment. How manufacturing developments are creating flexibility, addressing evolving delivery systems, maintaining sterility and implementing 100% automated inspection of some critical quality requirements will be discussed.

10:45 a.m. - 11:15 a.m.
Understanding Suitability of Materials and Components Used in Injectable Delivery Systems: The Extractables Leachables Factor
Diane Paskiet, Associate Director, Scientific Affairs, R&D, West Pharmaceutical Services, Inc.

11:15 a.m. - 11:45 a.m.
Applying a Risk-Based Approach for Prefilled Syringe Vendor Evaluation
Ivy Lin, Senior Engineer, Genentech, Inc.

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

10:45 a.m. - 12:15 a.m.
High Voltage Leak Detection for Container Closure Integrity Testing of Liquid Filled Primary Containers
Craig Goldhammer, Consultant Engineer, Eli Lilly and Company

11:15 a.m. - 11:45 a.m.
Insight into Injectable Device Assembly
Dena Flamm, Product Manager, Bosch

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

12:15 p.m. - 1:45 p.m.
Exhibit Area Closed - A listing of local restaurants is available in your conference materials
### Lunch Session: Stream A – The Impact of Packaging Choice and Design in Minimizing Point of Care Risks and Optimizing Patient Outcomes

**Moderator: Georg Roessling, PhD, Senior Vice President, PDA Europe**

Whether in a patient’s or clinician’s hands, the choice of device made by pharmaceutical companies for injectables can have a significant impact on patient outcomes, from minimizing point-of-care risks to helping ensure better chronic disease management. In this session, risk profile and human factors data, agency perspective and case studies will be presented to illustrate this impact.

### Lunch Session: Stream B – Enhancing Outcomes and Performance through Novel Drug Delivery Technologies

**Moderator: Richard Levy, PhD, Senior Vice President - Science & Regulatory Affairs, PDA**

In this session, various breakthrough PFS technologies developed to meet advanced delivery requirements will be discussed as well as design considerations for effective device integration and administration of large subcutaneous injections.

### A Focus on Clinician Administered Injectables - Minimizing Point-of-Care Risks Through Use of Advanced Drug Delivery Systems

**Ronald S. Litman**, Professor of Anesthesiology and Pediatrics, *Perelman School of Medicine at the University of Pennsylvania*

**Brian Lynch**, Program Lead – Health Science & Technology, Immunization, *BD Medical, Pharmaceutical Systems*

### A Focus on Patient Administered Injectables - The role of Human Factors Engineering in Enabling Successful Device Development and Disease Management

**Raza Ahmed, MD**, Worldwide Director, Medical Affairs, Self-Administration Injection Systems, *BD Medical, Pharmaceutical Systems*

### Overcoming Secondary Device Integration Barriers - Innovative Solutions for Enhanced Glass PFS Performance

**Theresa Bankston, PhD**, Manager, Bioanalytical & Pharmaceutical Development, *BD Medical, Pharmaceutical Systems*

### Overcoming the 1ml barrier - Delivering PFS Solutions for Subcutaneous Injections

**Herve Soukiassian**, Worldwide Cluster Leader, *BD Medical, Pharmaceutical Systems*

### Concurrent Sessions

#### A4 – Partnership Approaches Along Drug Life Cycle to Improve Patient Outcomes

**Moderator: Christian Helbig, Head of Global Business Development Syringe, SCHOTT Schweiz AG**

The industry is continuously fuelling innovations and improvements in the prefilled syringe space to improve patient outcomes. A critical success factor in implementation is how pharmaceutical company and supplier stem synergies through partnership. This session will share with attendees’ partnership approaches that have been employed to get new / improved delivery devices to patients.

#### B4 – Supply Chain Security

**Moderator: Adalberto Ramirez, Vice President, Quality, Amgen, Inc.**

Supply Chain security continues to be a hot topic for our industry. Many news events in this area make evident the need to align efforts, create awareness and be vigilant. Promoting the global supply chain integrity is a responsibility shared among all stakeholders. In this session, we will discuss the latest events and different measures taken by the industry and regulators. In addition, we will discuss how and why criminals and unethical players have Infiltrated the medicines Supply Chain and what we can do to counter attack and eliminate or neutralize them.
Pharmaceutical Systems
Kathleen O'Sullivan, Associate Director, Regulatory Affairs, BD Medical, Pharmaceutical Systems
2:45 p.m. - 3:15 p.m.
Questions and Answers/ Discussion

3:15 p.m. - 4:00 p.m.
Refreshment Break and Poster Presentations in Exhibit Area

4:00 p.m. - 5:30 p.m.
P4 - Global Market Trends
Moderator: Graham Reynolds, Vice President - Marketing and Innovation, West Pharmaceutical Services, Inc.
There are many factors which will drive and shape our industry in the coming years, and this session is designed to review some of the major trends. Geographic expansion, increased access to healthcare, patient-centric solutions and the growth of biosimilars are examples of some of the topics to be explored.

4:00 p.m. - 4:30 p.m.
Biosimilar/Product Delivery Systems
Mateja Urlep, Consultant, Tikhe Pharma

4:30 p.m. - 5:00 p.m.
Emerging Markets
Manoj Pananchukunnath, Head of Injectable Development, Mylan
Sponsored by West Pharmaceutical Services, Inc.

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

5:30 p.m.
Closing Remarks and Adjournment
Adalberto Ramirez, Vice President, Quality, Amgen, Inc.