2018 PDA Universe of Pre-Filled Syringes and Injection Devices

Transforming Pre-Filled Systems through Innovation

October 8-9, 2018 | Loews Royal Pacific | Orlando, FL

As of June 29, 2018

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 am. - 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.*
Session Description: 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 bring not only value to the patient but also bring real returns to the business. We will explore the Patient, the Pharma, the Payer and the Health care 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*

Session Description: Due to several market trends related to reducing healthcare cost, as well as a highly competitive market, pharmaceutical companies must find solutions which allow them to thrive in a cost sensitive environment. Companies must continue to deliver safe therapies which 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 how to manage your overall costs to deliver products to patients.

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, 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*	**B1: When Packaging Becomes More Than Packaging** **Moderator: Joel Cotten,** Business Development Director, *Aptar Pharma*
Session Description: In recent years, first Connected Health solutions linked to injectable drugs have been successfully launched to the market. While this are great achievement, questions remain on future market trends, regulatory expectation and the overall Ecosystem evolution. This session aims to reflect on the recent experiences and learnings with respect to the benefits delivered to patients as well as to the companies themselves.	**Session Description:** From a high-level perspective Packaging must protect the injectable drugs as well as the intermediate injection systems till they reach the final users, mostly patients and healthcare workers. It appears more and more than the pharmaceuticals packaging are embarking smart innovations that serve other purposes than just the physical protection. We propose to present in this packaging section 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. **Connected Health: Moving Beyond The Hype** **Kevin Deane,** Executive Vice President, Front-End Innovation, *Phillips-Medisize, a Molex Company*	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. **Wearable Injectors can Improve Patient Outcomes – A Case Study from Diabetes Management which 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*	2:00 p.m. – 2:30 p.m. **Using Smart Packaging to Enhance Supply Chain Quality of Drug Delivery Devices: How Smart Primary Packaging & 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**	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: Development **Moderator: Brigitte Reutter- Haerle,** Vice President, Marketing/Corporate Communications, *Vetter Pharma International*	**B2: Building Clarity in Addressing Regulatory Challenges for Combination Products** **Moderator: Fran DeGrazio,** Vice President, Scientific Affairs & Technical Services, *West Pharmaceutical Services, Inc.*
Session Description: 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.	**Session Description:** Prefilled syringes and delivery devices have unique challenges from a regulatory perspective. It is critical that both drug and device requirements be understood & executed. Additionally, as new innovations get implemented complexity is magnified. The speakers in this session will provide guidance that one can immediately use in addressing these issues.
3:45 p.m. – 4:15 p.m. **Integrating Control Strategy in Pharmaceutical & Device Development & Manufacturing for Combination Product Delivery Devices** **Ling Li,** Senior Principal Scientist**,** *Pfizer Inc.*	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*
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.*	4:15 p.m. – 4:45 p.m. **What's new with the 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**	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

Breakfast I: Innovation to Support Product Stability **Moderator: Brigitte Reutter- Haerle,** Vice President, Marketing/Corporate Communications, *Vetter Pharma International*	**Breakfast II: Case Studies: Leveraging Combination Product Platforms** **Moderator: Anthony L. Schaff, Sr., P.E.,** Senior Engineering Advisor, Delivery Device and Connected Systems, *Eli Lilly and Company*

Session Description: Innovations and improvements in development for injectable devices are critical to ensuring drug/device compatibility, safety and performance. Understanding mechanism of action that help to ensure proper deployment and functionality of such systems is vital to performance. This session offers attendees a two examples that can impact performance and mitigate future risk of compatibility that must be considered when evaluating product quality and stability.	**Session Description:** The effort to reduce development costs and to enable faster submission timelines can be facilitated by use of combination product platforms. This session will discuss how the use of platforms can benefit both Primary Container characterizatoin/qualification, and Delivery System usability validation.
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*, Glaxo Smith Kline* 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.*

Session Description: 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 they 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 Types 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

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 QbD** **Moderator: William Dierick,** Fellow, Science & Technology, *Terumo Europe N.V.*
Session Description: 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, container designs, and their impact on the drug product and drug product delivery.	**Session Description**: 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 in 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.
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*	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. **Flexible Primary Container Closure Systems: Reimagining the Future of Parenteral Drug Delivery** **Akshay Kamdar,** Associate Engineering Advisor / Group Leader, *Eli Lilly and Company*	11:15 a.m. – 11:45 a.m. **The Journey to a Pre-filled On-Body Injector** **Mark Lee,** Chief Technology Officer, *Flex*
11:45 a.m. – 12:15 p.m. **Questions and Answers/Discussion**	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

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

A4: Human Factors as a Learning Tool, Not just a Validation **Moderator: Nic Bowman,** Head of Devices CoE, *Pfizer Inc.*	**B4: Taking Advantage of New Simulation Opportunities to Speed up the Real-World Validation and Qualification Time of Aseptic Fill-Finish Equipment** **Moderator: Wenzel Novak, PhD,** Market Development Director, Pharma, *Optima Machinery Corporation*
Session Description: All drug delivery devices need to pass a summative human factors test before they can be approved and released onto the market. Like a driving test, a summative human factors study doesn't necessarily represent how you drive, or indeed, intend 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 and 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	**Session Description:** 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.

insight into usability and to guide device development to deliver highly usable devices patients need.	
1:30 p.m. – 2:00 p.m. **How to Prevent Medication Errors: An Experimental Study on Self-Injection Device Platform Distinguishability** **Andreas Schneider,** Innovation & Business Development Manager, *Ypsomed AG*	1:30 p.m. – 2:00 p.m. **Artificial Intelligence. Machine Learning. Deep Learning. Can these Technologies be Applied to Pharmaceutical Automatic Inspection Processes?** **Massimo Frasson**, General Manager, *Brevetti CEA Spa*
2:00 p.m. – 2:30 p.m. **Simulating Stressful, Emergency Use Scenarios During Injection Device Usability Tests** **Allison Strochlic,** Research Director, Human Factors, *UL LLC/ UL-Wiklund*	2:00 p.m. – 2:30 p.m. **Industry Representative Invited**
2:30 p.m. – 3:00 p.m. **Questions and Answers/Discussion**	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. **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*
Session Description: This session will discuss the changes of the EU MDR (Medical Device Regulation). This will change the requirements significantly also for DDCs (Drug Device Combinations = Combination Products) regarding additional submission requirements, increased involvement of notified body, and life cycle management of products. We will understand 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 of 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*