



## 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 October 3, 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 a.m. - 10:00 a.m.

**P1: Drug Delivery Innovations that Bring Value to both the Patient and the Business**

**Moderator: David Haase**, Senior Manager, Device Development, *Genentech, Inc.*

Innovations are exciting and bring new capabilities, but they may also bring added costs. In this session we will focus on a few of the recent connected device innovations and see how they 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.

**The Triumvirate Designing for Healthcare's 3 Masters**

**Kai Worrell**, CEO, *Worrell Design Inc.*

9:00 a.m. - 9:30 a.m.

**How Connected Devices and Digital Health Innovations are Bringing Value-Based Care Across the Healthcare Ecosystem**

**Paul Geevarghese**, Vice President, Market Access North America, *mySugr, A Member of the Roche 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**

The following posters will be presented during today's refreshment breaks

1. **High-Performance Syringe System dedicated to Biopharmaceuticals: A Closure System with Non-Siliconized COP and Glass Syringe Plugged by a Newly Developed Stopper, to Reduce Any Particulates Including Aggregation such as Subvisible Particle and Invisible Particle**  
Yoshihiko Ikeguchi, PhD, Manager, *Taisei Kako Co., Ltd.*
2. **Thermal Test Bench to Accelerate Drug and Delivery Device Development - ISO 11608 Testing**  
Andy Rogers, VP of Business Development, *Key Tech*  
Michael C. Song, PhD, Senior Manager, *MedImmune/AstraZeneca*
3. **Verification of Formation Process of Aggregates by Flow Imaging Method**  
Saki Yoneda, Master Course Student, *Osaka university*
4. **Stability of Pharmaceutical Proteins in Pre-Filled Syringes Made of Cyclo Olefin Polymer (COP)**  
Taichi Sawaguchi, Chief Researcher, *ZEON Corporation*
5. **Science of Drug-Packaging Interactions and Predictive Approaches to Successfully Select the Right Container and Materials for Biological Formulations**  
Claire Brunet, PhD, Principal Scientist, Research & Development, *Becton Dickinson*
6. **What Plastic Bags Can Do to our Devices: Something you Might Have Never Heard Before**  
Hemant Amarchinta, PhD, Senior Engineer, Device Development, *Genentech, A Member of the Roche Group*
7. **Market Trends and Considerations for Improving the Patient Experience and Outcomes Through Training**  
Joe Reynolds, Market Intelligence Manager, *Noble*
8. **Development of Tissue Resistive Pressure During Subcutaneous Injection: Unveiling the Mechanism and Behavior Using a Novel First Principle Model**  
Ali Nekouzadeh, PhD, Senior Engineer, *Amgen Inc.*
9. **Effect of Container Surface on Adsorption and Aggregation of Protein Therapeutics**  
Ranjana Singh, PhD, Senior Scientist, *West Pharmaceuticals, Inc.*
10. **Multilayer Plastic Syringe with High Gas Barrier, Low Extractables, and High UV Barrier**  
Takuya Minezaki, Research Manager, *Mitsubishi Gas Chemical Company, Inc.*
11. **From Quality by Design to Commercial Readiness: A New Option for Silicone Sensitivity**  
Christiane Gumera, PhD, Product Specialist, *W.L. Gore & Associates, Inc.*
12. **Migration Study to Evaluate the Impact of Steam vs. Gamma Irradiation in Ready-To-Use (RTU) Uncoated Stoppers and Fluorinated (ETFE) Film Coated Stoppers**  
Michael J. Mayer, Senior Scientist, *Next Breath*
13. **Establishing a Market Leading Answer to a Reduced Particulates Profile for Elastomeric Solution**  
Arnaud Fournier, Senior Business Project Manager, *Aptar Pharma*
15. **Gx RTF Syringes and Novapure Plungers: A New 1-3 mL Syringe System Well Suited for Silicone Sensitive Formulations**  
Maximilian Vogl, Global Head of Product Management Gx® Solutions, *Gerresheimer Bünde GmbH*
16. **The Correlations Between Viscosity, Needle Diameter, Flow Rate and Dose Accuracy in a Patch Pump Therapy**  
Michael Girschweiler, Technology Manager, *Sensile Medical AG*
17. **In-vivo Flowrate Modeling based on In-vitro Performance for the Enable On-Body Delivery Device**  
Matthew J. Huddleston, Executive Vice President and Chief Technology Officer, *Enable Injections*
18. **Effects of Product Handling Parameters on Particle Levels in a Commercial Factor VIII Product: Impacts and Mitigation**  
Tsutomu Ueda, Research Manager, *Terumo Corporation*
19. **The Importance of Characterising Drug Delivery When Meeting the Human Needs of a High Viscosity Autoinjector**  
Jonathan Bradshaw, MSc, Device Development Engineer, *Oval Medical Technologies*

10:45 a.m. – 12:15 p.m.

**P2: Overcoming the Challenges of a Cost-Controlled Environment**

**Moderator: Theresa Bankston, PhD**, Director, Technical Services, *BD Medical – Pharmaceutical Systems*

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**, Senior Manager, External Supply, *Amgen Inc.*

**Marcelo Abad Landa**, Senior Director, WW Manufacturing, *Becton Dickinson*

11:15 a.m. – 11:45 a.m.

**How Come Outcomes? The Emerging Importance of Value Based Drug Delivery**

**Justin Wright, PhD**, Global Head of Innovation, *Novartis*

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**

<b>A1: Drug Delivery within the Digital Health Ecosystem: Where do we Stand?</b> <b>Moderator: Christian Helbig</b> , Head of Strategic Business Field Glass Syringes, <i>SCHOTT Schweiz AG</i>	<b>B1: When Packaging Becomes More Than Packaging</b> <b>Moderator: Joel Cotten</b> , Business Development Director, <i>Aptar Pharma</i>
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.	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. <b>Connected Health: Moving Beyond The Hype</b> <b>Kevin Deane</b> , Executive Vice President, Front End Innovation, <i>Phillips-Medisize</i>	1:30 p.m. – 2:00 p.m. <b>Case Study: Implementation of an Innovative High-Speed Laser-Marking Solution on Glass Pre-Filled Syringes</b> <b>Teddy Klein</b> , Global Engineering, Technology Program Leader, <i>Sanofi Pasteur</i> <b>Patrick Jeukenne</b> , VP Strategy, Pharma Segment, <i>Aptar Pharma</i>
2:00 p.m. – 2:30 p.m. <b>Wearable Injectors can Improve Patient Outcomes: A Case Study from Diabetes Management which can be Leveraged for Wearable Injector Platforms for Biologic Drugs</b> <b>Anil Busimi</b> , Senior Global Product Manager, <i>SCHOTT AG</i> <b>David Henderson</b> , Director of Operations, <i>Beta Bionics, Inc.</i>	2:00 p.m. – 2:30 p.m. <b>Using Smart Packaging to Enhance Supply Chain Quality of Drug Delivery Devices: How Smart Primary Packaging &amp; Object Aware Machinery Can Lead to Better Quality Outcomes</b> <b>Markus Bauss</b> , Managing Director, <i>SHL Connect, SHL Group</i> <b>Egmont Semmler, PhD</b> , Director, Research & Development, <i>Groninger &amp; Co. GmbH</i>
2:30 p.m. – 3:00 p.m. <b>Questions and Answers/Discussion</b>	2:30 p.m. – 3:00 p.m. <b>Questions and Answers/Discussion</b>

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**

<b>A2: Development</b> <b>Moderator: Brigitte Reutter- Haerle</b> , Vice President, Marketing/Corporate Communications, <i>Vetter Pharma International</i>	<b>B2: Building Clarity in Addressing Regulatory Challenges for Combination Products</b> <b>Moderator: Fran DeGrazio</b> , Vice President, Scientific Affairs & Technical Services, <i>West Pharmaceutical Services, Inc.</i>
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.	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. <b>Integrating Control Strategy in Pharmaceutical &amp; Device Development &amp; Manufacturing for Combination Product Delivery Devices</b> <b>Ling Lu</b> , Senior Principal Scientist, <i>Pfizer Inc.</i>	3:45 p.m. – 4:15 p.m. <b>Challenges and Opportunities with Applying Device Software Regulation in a Drug Setting</b> <b>Chin-Wei Soo, DRSc</b> , Global Regulatory Head, Combination Products and Devices, <i>Genentech, A Member of the Roche Group</i>
4:15 p.m. – 4:45 p.m. <b>Implementation of Quality requirements in Manufacturing of Clinical Phase I/II Drug Product</b> <b>Natasha Rivas</b> , Director Quality Assurance and Quality Control, <i>Vetter Development Services USA, Inc.</i>	4:15 p.m. – 4:45 p.m. <b>What's new with the Regulations? A Well-Rounded Approach to Regulatory Performance Testing for Combination Products</b> <b>Daniel L. Bantz</b> , Technology Manager, <i>West Pharmaceutical Services, Inc.</i>
4:45 p.m. – 5:15 p.m. <b>Questions and Answers/Discussion</b>	4:45 p.m. – 5:15 p.m. <b>Questions and Answers/Discussion</b>

7:00 p.m. – 10:00 p.m.

**Networking Reception** – Sponsored in Part by *Owen Mumford, Sensile Medical and MedImmune*

**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**

<p><b>Breakfast I: Innovation to Support Product Stability</b> <b>Moderator: Brigitte Reutter- Haerle</b>, Vice President, Marketing/Corporate Communications, <i>Vetter Pharma International</i></p>	<p><b>Breakfast II: Case Studies: Leveraging Combination Product Platforms</b> <b>Moderator: Anthony L. Schaff, Sr., P.E.</b>, Senior Engineering Advisor, Delivery Device and Connected Systems, <i>Eli Lilly and Company</i></p>
<p><b>Session Description:</b> 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.</p>	<p><b>Session Description:</b> 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 characterization/qualification, and Delivery System usability validation.</p>
<p>7:15 a.m. – 7:40 a.m. <b>Compatibility Risk of Drug Formulation and Syringe/Autoinjector Functionality</b> <b>Galen Shi, PhD</b>, Advisor, <i>Eli Lilly and Company</i> <b>Liang Fang</b>, Principal Research Scientist, <i>West Pharmaceutical Services, Inc.</i></p> <p>7:40 a.m. – 8:05 a.m. <b>Evaluation of a Silicone Free Syringe and Stopper Presentation for Use in Biopharmaceutical Drug Product Development</b> <b>Caitlyn J. Sofa</b>, Senior Scientist, <i>GlaxoSmithKline</i></p> <p>8:05 a.m. – 8:15 a.m. <b>Questions and Answers/ Discussion</b></p>	<p>7:15 a.m. – 7:40 a.m. <b>An Approach to Design and Develop a Platform Primary Packaging System for Parenteral Combination Products</b> <b>James K. Mellman, PhD</b>, Device Manager, <i>Novartis</i></p> <p>7:40 a.m. – 8:05 a.m. <b>Simplify your Usability Validation: Introducing a Novel Approach for Validating Platform Device Usability</b> <b>Christoph Jordi</b>, Senior Usability Manager, <i>Ypsomed AG</i> <b>Allison Y. Strohlic, MS, CHFP</b>, Research Director, Human Factors Research &amp; Design, <i>UL LLC / UL-Wiklund</i></p> <p>8:05 a.m. – 8:15 a.m. <b>Questions and Answers/ Discussion</b></p>

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, Smart Device Technology Center, *Roche/Genentech*

9:00 a.m. – 9:30 a.m.

**Investigating the Link between Patient Personality Dimensions and Causes of Non-Adherence**

**Claire Everitt**, Design Engineering, Lead, *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**

Poster Presentations | Pacifica Ballroom 1-7

The following posters will be presented during today's refreshment breaks

1. **Partnering with Pharma: Maximizing Strategic Relationships to Minimize Product Development Timelines and Commercialization Risk to Focus on Patient Convenience Initiatives**  
Jeannie Joughin, PhD, EVP and Chief Commercial Officer, *Enable Injections*
2. **Developing an Effective Primary Drug Container System Which Manages the Requirements of Highly Viscous Formulations**  
Susanna White, Meng, Device Development Engineer, *Oval Medical Technologies*
3. **Fluoroscopic Imaging In Vivo Model of Large Volume Subcutaneous Injection Depot Dispersal**  
Wendy D. Woodley, Staff Scientist, *BD Technologies*
4. **Ready-to-Use Pre-Filled Syringes for Ophthalmic Drugs**  
Christopher Weikart, PhD, Chief Scientist, *SIO2 Medical Products, Inc.*
5. **A Patient-Centric Design Thinking and Co-Creation Approach for Novel Injection Device Development**  
Herve Monchoix, Strategic Innovation Leader, *BD Medical - Pharmaceutical Systems*
6. **Development and Implementation of Combination Product Control Strategies**  
Mathieu Rigollet, Senior Pre-filled Syringe Engineer, *F. Hoffmann-La Roche Ltd.*
7. **Initial Report of Micro-Projection Silicone-Oil Free Plunger Stopper (Micro-Projection Plunger Stopper, MP-PS\_SOF) That Has Developed New Technology Based on Conventional Full-Laminated Plunger Stopper**  
Yuki Sakashita, R&D Engineer, *Sumitomo Rubber Industries, Ltd.*
8. **Pre-Filled, Pre-Loaded Wearable Injector with Inbuilt Auto-Reconstitution: A Revolution in the Making**  
David Staub, Medical Device Development Project Manager, *Sonceboz SA*
9. **CMO Case Study: The Manufacturing Impact in the Adoption of an Integrated Safety System on Pre-Filled Syringes**  
Alessandro Morandotti, Product Manager, *Ompi – Stevanato Group*
10. **Disinfection at Point of Care for Prefilled Wearable Drug Delivery Devices**  
Ori Ben-David, PhD, Director of R&D, *Sorrel Medical*  
Andrei Yosef, PhD, CEO, *Sorrel Medical*
11. **Lyophilization in Pre-Filled Syringes: Evaluating the Influence of Primary Container Material and Loading Device**  
Kevin N. Constable, Senior Director, Technology Development, *Terumo Pharmaceutical Solutions*
12. **Characterization of the Minipig for Subcutaneous Administration of Biotherapeutics**  
Tonio R. Hoche, Device Engineer, *F. Hoffmann-La Roche Ltd.*
13. **Feasibility Study Designed to Assess the Most Suitable On-Body Delivery System, that Best Meets Drug Product Properties and Delivery Profile Requirements**  
Reut Atarot, Project Manager, *West Pharmaceutical Services, Inc.*
14. **Parenteral Delivery Devices – Three Key Trends, Challenges, and Opportunities**  
John Burke, Senior Consultant, *Team Consulting Ltd*
15. **Aging of Complex Systems: Fundamental Theory and Implications in the Aging of Primary Containers and Medical Devices Components and Totality**  
Nestor Rodriguez, Senior Staff Scientist, *Becton Dickinson – Pharmaceutical Systems*
16. **Benefits of Early integration of Human Factors: A Case study**  
Josie Wright, Principal Engineer, *AstraZeneca*
17. **Comparison of Dow Corning Emulsions DC 365 and DC 366 Concerning Emulsions Stability and Final Product Quality of Siliconized Containers for Protein Formulations**  
Fabian A. Moll, Pharmacist/Research Assistant, *Ludwig Maximilian University of Munich*
18. **Case Study: Leveraging Visual Inspection Data to Reduce Process Variation in Pre-Filled Syringe Production**  
Philipp Sommerfeld, Process Engineer Filling, *Roche Diagnostics GmbH*
19. **Human Factors Considerations in Evaluating On-Body Medical Device Adhesive Components**  
Rachel C. Talbott, MS, Human Factors Engineer, *Enable Injections*

10:45 a.m. – 12:15 p.m.

**Concurrent Sessions**

<b>A3: Impact of Materials and Geometry on Primary Containers</b> <b>Moderator: Olivia Henderson, PhD</b> , Principal Engineer, <i>Amgen Inc.</i>	<b>B3: Quality Planning and QbD</b> <b>Moderator: William Dierick</b> , Fellow, Science & Technology, <i>Terumo Europe N.V.</i>
<b>Session Description:</b> 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.	<b>Session Description:</b> 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. <b>Impulsively-Generated Pressure and Strain Waves in Pre-Filled Syringes During Autoinjector Activation</b> <b>Julian Jazayeri</b> , Senior Engineer, <i>Amgen Inc.</i> <b>Jean Christophe Veilleux</b> , PhD Candidate, <i>California Institute of Technology</i>	10:45 a.m. – 11:15 a.m. <b>Building a Strong Bridge to Support Device Changes or New Product Presentations</b> <b>Sherri Biondi, PhD</b> , Senior Director, Device Development, <i>MedImmune</i>
11:15 a.m. – 11:45 a.m. <b>Flexible Primary Container Closure Systems: Reimagining the Future of Parenteral Drug Delivery</b> <b>Akshay R. Kamdar, PhD</b> , Engineering Advisor / Group Leader, <i>Eli Lilly and Company</i>	11:15 a.m. – 11:45 a.m. <b>The Journey to a Pre-Filled On-Body Injector</b> <b>Tommaso Borghi, PhD</b> , Design Program Manager, <i>Flex</i>
11:45 a.m. – 12:15 p.m. <b>Questions and Answers/Discussion</b>	11:45 a.m. – 12:15 p.m. <b>Questions and Answers/Discussion</b>

12:15 p.m. – 1:30 p.m.

**Networking Lunch in Exhibit Hall**

1:30 p.m. – 3:00 p.m.

**Concurrent Sessions**

<b>A4: Human Factors as a Learning Tool, Not just a Validation</b> <b>Moderator: Nic Bowman</b> , Head of Devices CoE, <i>Pfizer Inc.</i>	<b>B4: Validation and Qualification Effects on Time to Market of Aseptic Fill-Finish Processes</b> <b>Moderator: Wenzel Novak, PhD</b> , Global Senior Director, Business Development, Medical Device Systems, <i>Gerresheimer Buende GmbH</i>
<b>Session Description:</b> 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	<b>Session Description:</b> Blockbuster strategies no longer drive the market of equipment. New approaches ask for a high variability on containers, processes and an increasing variety of products are 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, thinking / calculating ahead of the trials and even the use of artificial intelligence allows 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 theoretical 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. <b>How to Prevent Medication Errors: An Experimental Study on Self-Injection Device Platform Distinguishability</b> <b>Andreas E. Schneider, PhD</b> , Innovation & Business Development Manager, <i>Ypsomed AG</i>	1:30 p.m. – 2:00 p.m. <b>Bubble-Free Filling of RTU Pre-Capped Cartridges</b> <b>Daniel Kehl, CEO, Swissfillon AG</b> <b>Enrico Zanetti</b> , Sales & Business Development Manager, <i>Swissfillon AG</i>
2:00 p.m. – 2:30 p.m. <b>Simulating Stressful, Emergency Use Scenarios During Injection Device Usability Tests</b> <b>Allison Y. Strohlic, MS, CHFP</b> , Research Director, Human Factors Research & Design, <i>UL LLC / UL-Wiklund</i>	2:00 p.m. – 2:30 p.m. <b>Artificial Intelligence. Machine Learning. Deep Learning. Can These Technologies Be Applied to Pharmaceutical Automatic Inspection Processes?</b> <b>Massimo Frasson, PhD</b> , General Manager, <i>Brevetti CEA Spa</i>
2:30 p.m. – 3:00 p.m. <b>Questions and Answers/Discussion</b>	2:30 p.m. – 3:00 p.m. <b>Questions and Answers/Discussion</b>

3:00 p.m. - 3:45 p.m.

**Refreshment Break and Poster Presentations in Exhibit Hall**

3:45 p.m. - 5:15 p.m. <b>P4: A New Era for Medical Devices and Combination Products. What is the Impact?</b> <b>Moderator: Manfred Maeder, PhD</b> , Head Devices & Combination Products, <i>Novartis Pharma AG</i>
<b>Session Description:</b> 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. <b>The New MDR and Article 117: An Industry Perspective</b> <b>Marc Rohrschneider, PhD</b> , Head New Technologies, <i>Novartis Pharma AG</i>
4:15 p.m. - 4:45 p.m. <b>Update on Changes to the EU MDR</b> <b>Girish Kumar, PhD</b> , Product Specialist, <i>TÜV SÜD America</i>
4:45 p.m. - 5:15 p.m. <b>Questions and Answers/ Discussion</b>

5:15 p.m.

**Closing Remarks from Committee Co-Chair**

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