Pre-filled Syringes & Auto-Injectors Virtual Forum 2020
September 23–24, 2020, Online, Eastern Daylight Time

Featuring Lessons Learned & Case Studies From Industry Experts:

- Understanding the Implications of the New FDA Guidance on Bridging for Drug-Device and Biologic-Device Combination Products
- Transitioning to the New EU MDRs—What You Need to Know
- Electronically Powered Drug Delivery Devices: Considerations and Challenges
- Human Factors—Translating User Research to Actionable Product Specification
- Broadening Patient Access to Clinical Studies for Self-Administered Medications (PFS And Autoinjector)

And Comprehensive Coverage On:

- Biological Drugs Differentiated by Injection Devices: Recent Trends in Auto-Injectors and Connectivity
- Strategic Development of Auto-Injectors—What the Future Holds
- Stability Strategies for Parenteral Platforms
- Best Practices in Manufacturing & Processing
- Platform-based Combination Products for Self-Injection
- A System-Wide Approach to Stability of Combination Products
- Control Strategy and Design Transfer for PFS and Auto-Injectors
- Integrated Development and Risk Management Process for Parenteral Products
- Risk Management Best Practices for Drug Delivery Combination Product Life Cycle
- Long-Term Functional Stability Testing of Safety Syringe and Autoinjection Devices: A Case Study for a High-Concentration Mab Product
- Syringe Second Source Initiative: A Dual Source Identification to Reduce Supply Risk
- And More!

With Representation From:

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Drug Development  drugDELIVERY
Drug Delivery Device Technology
Spotlight—Challenges and Opportunities in Connected Health

Martin McLaughlin, Head of Device Development, Bristol-Myers Squibb

Drug delivery devices occupy a unique place in healthcare ecosystems because they are guaranteed to be present at the point-of-care, so that in addition to their primary function, they can serve a secondary function as a point-of-care data communications terminal. Also, the miniaturization and commoditization of electronic components, and the rise of smartphone technology and wireless communication networks and protocols has led to new opportunities in their design which range from simple electronic dose counters to sophisticated microprocessor control systems integrated with feedback from real-time biomarker measurements. However, these opportunities come with challenges across the economic, legal, regulatory and technical realms. This presentation will provide a brief history and a survey of the current state-of-the-art with some selected examples, followed by a discussion of the challenges, focusing on the technical, and some predictions for the future.

Biological Drugs Differentiated by Injection Devices: Recent Trends in Auto-Injectors and Connectivity

Robin Hwang, Founder, ICP Consulting

Biological drugs have been commercialized for decades with great success. Rapid growth and increased competition in biological markets has driven improvements in injection devices, mainly for autoinjectors. The product differentiation is increasingly becoming more important for many biotech companies to preserve and/or gain market shares. This talk will provide examples and trends on how leading biotech companies (both innovators and biosimilars) are differentiating biological drugs to gain better market acceptance through novel injection device technologies. The injection devices and device-with-connectivity will be discussed. The audience will learn the importance of injection devices and the newest trends in connectivity for differentiating biologics.

Critical Issues—Spotlight on Human Factors in PFS & Auto-Injectors

Katie Hansbro, CEO, Design Science Consulting

New quantitative and qualitative methods for understanding the multi-factor nature of experiential worlds are flourishing. Contextual inquiry, focus groups and usability studies are just a few of the tools available to combination product development teams. But how should they strike the right balance? In this talk, we examine mixed-methods research conducted on behalf of pharmaceutical companies. By approaching customers’ worlds from multiple angles, our case studies demonstrate how to harness numerous, often conflicting, methods to drive innovative solutions.

Critical Issues—Improving Patient Participation in Clinical Studies

Shawn Malloy, Associate Director, Curebase

Self-administration of parenteral solutions is a continually increasing trend in both commercial and clinical trial settings. Refinement of PFS and autoinjector technology has enabled this more patient centered administration paradigm in the comfort of patient’s homes or on the go. Unfortunately, the way clinical studies are operated have been slow to keep up with the changing administration environment. Clinical studies are typically conducted in a highly centralized fashion, where patients are required to drive hundreds of miles at times to central prestigious medical institutions to participate in a clinical study. The degree of manual study paperwork and dependence on few centralized sites is largely responsible for this current environment. There exists an opportunity to use modern digital technology and telecommunication to enable clinical study participation wherever people live. Curebase has demonstrated a proven model of enabling broader and more diverse participation in clinical research with several case studies. Curebase is now seeking to apply this model to more complex self-administration therapies to broaden access and reduce patient burden.

Lunch Hour. Visit the event chat-room.
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#### Regulatory Spotlight—Meeting Recent Regulatory Guidelines From FDA and EU MDRs

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<tr>
<td>1:00</td>
<td>US Regulatory Expectations for Pre-filled Syringes and Auto-Injectors, Including the New FDA Guidance on Bridging for Drug Devices and Biologic Devices</td>
<td>Bob Laughner, Regulatory Director, Medical Device and Combination Products, AstraZeneca</td>
<td>Abstract Coming Soon</td>
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<tr>
<td>1:35</td>
<td>EU MDR Impact on Premarket Regulatory Requirements for Combination Products</td>
<td>Jason Lipman, Director, Regulatory Affairs, Sanofi</td>
<td>Compliance with EU MDR Article 117 requires significant changes in practice and could impact combination product development timelines. This session will provide an overview of the new requirements, learnings from EMA and Notified Bodies, and industry’s current interpretations and approaches to meet the new requirements.</td>
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<td>2:10</td>
<td>Panel Discussion: The Changing Regulatory Landscape for Combination Products—What You Need To Know</td>
<td>Panelists: Bob Laughner, AstraZeneca, Jason Lipman, Sanofi</td>
<td>Discussants: The Audience</td>
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<td>2:45</td>
<td>Networking Break. Visit the event chat-room.</td>
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<td>3:05</td>
<td>Syringe Discoloration, Heavy Metals, and ICP-MS: A Case Study</td>
<td>Allen Kesselring, CSO, EKG Life Science Solutions</td>
<td>Elemental impurities analysis encompasses trace metal/heavy metal testing to evaluate pharmaceutical products for elevated concentrations of elements that are of significant toxicological concern. Based on ICH guidelines, the United States Pharmacopoeia (USP) has published general chapters &lt;232&gt; “Elemental Impurities—Limits” and &lt;233&gt; “Elemental Impurities—Proce-</td>
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<td>3:45</td>
<td>Syringe Second Source Initiative: A Dual Source Identification to Reduce Supply Risk</td>
<td>Nathan Heacock, Product Development Scientist, Glaxo Smith Kline</td>
<td>Abstract Coming Soon</td>
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<td>4:25</td>
<td>End of Day One</td>
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#### Thursday, September 24, 2020, Eastern Daylight Time

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<td>8:15</td>
<td>Pharma Ed welcome and opening remarks</td>
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<td>8:30</td>
<td>Case Studies in Launching Platforms for Big and Small Pharma</td>
<td>Steven Badelt, Ph.D., Managing Partner, Suttons Creek</td>
<td>The term platform has been promoted within the drug delivery marketplace with multiple interpretations and implications for both pharmaceutical companies and their suppliers. The nuances for execution with “platform” are different for well-established pharma with large device teams and for small pharma who have never launched a combination product. In this presentation, we will discuss the circumstances and lessons learned in case studies across large and small pharma, with both internal and external development projects. The materials presented will provide common challenges in project</td>
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pre-filled syringes & auto-injectors virtual forum 2020

9:10 development of platform-based combination products for self-injection

jakob lange, senior director, delivery systems, ypsomed ag

this presentation will provide an introduction to devices for self-injection with a market overview, and then explain the following topics:

• what is the platform approach?
• device development as part of the overall drug development program
• selecting the right device and vendor: how much customization?
• when to start device development
• case study: determination of acceptable use forces for device handling

9:50 primary packaging and injection systems for biopharmaceuticals: the role of an integrated approach from design to final device assembly

howard drake, vice-president business development and relationship management us, stevanato group

prefilled syringes are the industry’s choice of platform to further innovate drug products. because injectable biologics are complex, there are several aspects to consider, such as delivery methods, design of primary packaging, device and analysis of product stability, safety and efficacy. a system approach is needed, because of the interaction of biodrugs with drug delivery devices—such as autoinjectors—and syringes with different geometries and elemental compositions. all these are critical aspects to carefully evaluate in order to guarantee effective, safe and painless injection to the patient. drug development programs are requiring a certain degree of flexibility from early phase to commercialization, with the goal of reducing timing and investments. this presentation will provide an overview of the integrated approach involved in the different development stages: starting from primary packaging selection, system design, testing and process scalability from clinical phase to commercialization.

10:30 networking break. visit the event chat-room.

10:50 panel discussion: product development—meeting challenges, seizing opportunities

panelists:
• steven badelt, sutton’s creek
• jakob lange, ypsomed ag
• howard drake, stevanato group

discussants:
• the audience

technology spotlight—performance considerations for pfs & ai: two case studies

11:25 performance characterization of two different autoinjectors

kevin duffy, senior engineer consultant, eli lilly & co.

autoinjectors provide convenience to patients as an efficient way to self-administer subcutaneous injections of bolus biologics and pharmaceuticals. many of these treatments require regular injections by a spring-actuated, prefilled, single-dose disposable autoinjector. findings from this study breakdown key user interface elements of two different autoinjector designs, generating thoughtful insights. the current work presents a novel experimental study which integrates simultaneous measurements of force profiles, audible dose confirmation of injection completion, ultra-high speed imaging of the needle insertion and drug injection processes. this presentation provides a tangible analysis and performance comparison between two marketed autoinjector designs as well as implying the effects on user comfort and confidence that the device has delivered their complete dose.

12:10 lunch hour. visit the event chat-room.

1:10 considerations in primary packaging component selection for parenteral drug delivery

eugene polini, technical key account manager, datwyler sealing solutions

the component selection process is a critical step in developing safe and effective primary packaging for pharmaceutical and biotech drugs. considerations in component selection may involve evaluating a variety of elastomer compounds, assessing the need for additional protection through elastomer coatings, and establishing the best final seal, if applicable, to ensure the packaging maintains the drug product integrity.
Developing parenteral packaging is a complex process and the packaging components can be as important as the live-saving drugs themselves. These critical components could determine the success or failure of a drug product's approval. Partnering with industry experts allows for the mitigation of risks during component selection and provides a comprehensive analysis for the ideal sealing solution for each individual drug product.

Tale of Two PFS Manufacturing Process Considerations—Leakage and Clogging

*Yuh-Fun Maa, Senior Principal Engineer, Genentech*

This presentation covers two pre-filled syringe manufacturing process related case studies. The first study depicts an interesting phenomenon associated with liquid leakage (dripping) upon the removal of the PFS needle shield. Changes of air pressure in the headspace are the root cause for leakage. Physical attributes in relation to manufacturing processes were evaluated and approaches to minimizing leakage were proposed. The second case study highlights a process development approach for filling high-concentration antibody formulations in minimizing the risk of filling needle clogging which may deteriorate filling process robustness and potentially affect product quality.

Critical Issues—Risk Management Across Product Life-Cycles

1:40

**Exploring Risk Management Best Practices for Drug Delivery Combination Product Life Cycle**

*Fubin Wu, Co-Founder, GessNet*

Risk management plays a key role for the safety, quality, compliance, premarket approval and life cycle management of combination products. Effective risk management provides critical design inputs, proactively identifies and mitigates potential safety/quality issues, enables risk driven development and manufacturing practices, and tells a convincing story of safety/quality to stakeholders such as regulatory agencies or notified bodies.

This presentation will walkthrough risk management principles, and how the effective risk management can be implemented through the combination product life cycle. This includes analysis of common pitfalls and introduction of solutions such as risk analysis, reporting, and monitoring tools. Additional examples will be provided showing how risk management findings are related to CTQ, Essential Performance, Reliability, and Control Strategy.

3:10

**Technical Data Update: Cyclo Olefin Polymer (COP) For Prefilled Syringes**

*Toshiro Katayama*

After a brief review of COP properties, this presentation will discuss three new case studies comparing COP with typical glass container closures and new leachable data on COP syringes. Areas to be covered include:

- Key properties of COP
- Case Study (New):
  - Protein Adsorption of Abatacept – COP vs Glass
  - Immunogenicity test of the aggregates
- Case Study: Protein Adsorption of Humira, Embrel, Remicade – COP vs Glass
- Case Study: Protein Adsorption with/without Polysorbate (Surfactant) – COP vs Glass
- Leachable data on COP syringes

3:50

Close of Program
In the Age of COVID, the Show Must Go Online
In response to overwhelming audience and speaker feedback, and in view of the current health and safety concerns involving the novel coronavirus COVID-19, we’re taking our events online (at least for the foreseeable future; we do hope to see you again soon in person when all this is over!) Pre-filled Syringes & Auto Injectors Virtual Forum 2020 is an entirely online event, complete with insightful presentations from leading researchers, 1:1 networking opportunities, live question & answer sessions, and sponsored informational presentations that highlight how vendors are tackling some of the key issues facing parenteral device market. Just sit back and enjoy this online learning experience from the safety and comfort of your home or office. Missed a session or two? No worries—the full program will be archived and available for post-conference viewing and download.

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