PharmaED RESOURCES, Inc.

Pre-filled Syringes & Auto-Injectors Virtual Forum 2020

September 23–24, 2020, Online, Eastern Daylight Time

Featuring Lessons Learned & Case Studies From Industry Experts:

Steven Badelt (Chair)
Founder
Sutton's Creek

Martin McLaughlin
Head of Device Development
Bristol-Myers Squibb

Kathryn Hansbro
CEO
Design Science Consulting

Jason Lipman
Director, Regulatory Affairs
Sanofi

George Cusatis
Director, Device & Digital Health
Merck

Yuh-Fun Maa
Sr. Principal Engineer
Genentech

Kevin Duffy
Sr. Engineer
Eli Lilly & Co.

James Scull
Scientific Director
Element Health Sciences

Allen Kesselring
CSO
EKG Life Science Solutions

Howard Drake
VP
Stevanato Group

Fubin Wu
Co-Founder
GessNet

Toshiro Katayama
Product Manager
Zeon

Eugene Polini
Technical Key Acct. Mgr.
Datwyler

Joe Barco
Senior Director
Unchained Labs

Robin Hwang
Founder
ICP Consulting

And Comprehensive Coverage On:

- 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)
- 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 Autoinjector 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 & Delivery

10 ON drugDELIVERY
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Wednesday, September 23, 2020, *Eastern Daylight Time*

8:45 *Chairperson's welcome & opening remarks*

Steven Badelt, Founder, Sutton's Creek

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

9:00

Electronically Powered Drug Delivery Devices: Considerations and Challenges

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.

9:45

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.

10:25 *Morning Break & Sponsor Presentations*

element Jordi Labs EKG Labs

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

10:45

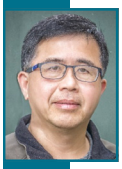
The Mixed Methods Minefield: Innovation in Combination Product HF Research Services

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.

11:30

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.

12:10 *Lunch Hour. Visit the networking chatroom.*

1:10

Plastic Ingenuity Presentation

Speaker to be announced.

Abstract to come.

1:30

EU MDR Impact on Premarket Regulatory Requirements for Combination Products

Jason Lipman, Director, Regulatory Affairs, Sanofi

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.

2:10

The Utilization of Regulatory Intelligence in the Evolving Global Landscape for Combination Products, Medical Devices, and Digital Health Solutions

George Cusatis, Director, Device & Digital Health, Merck

In recent years, management teams have requested regulatory intelligence functions to illustrate the value added to the collective company and to individual product success. In many cases relevant findings cannot be measured until much later, such as once a product has been developed and received approval or a final guidance is re- leased. Regulatory intelligence teams exhibit value through a variety of metrics including number of comments sub- mitted or FDA meetings conducted and although these are important evaluations, meaningful significance is added when these figures are linked to affecting a final guidance released by the FDA or the organization saving resources due to faster time to market or overall reduced costs.

- Analysis of qualitative vs. quantitative measurements
- Tracking comments to view effect on final guidance
- Demonstrating reduced costs due to collected data

2:50 *Afternoon Break & Sponsor Presentations*

DATWYLER Plastic Ingenuity ZEON

3:10

Panel Discussion: The Changing Regulatory Landscape for Combination Products—What You Need To Know

Moderator: Steven *Badelt*, Sutton's Creek

Panelists:

- Jason Lipman, Sanofi
- George Cusatis, Merck

Discussants:

- The Audience

3:50

Syringe Discoloration, Heavy Metals, and ICP-MS: A Case Study

Allen Kesselring, CSO, EKG Life Science Solutions

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 <232> "Elemental Impurities—Limits" and <233> "Elemental Impurities—Procedures". While these chapters are designed specifically for drug products themselves, the FDA *continues to expand* their regulation of container closure systems and packaging associated with pharmaceuticals. A key way to mitigate risk is to perform an exhaustive extractable/leachable (E&L) study prior to drug product use. Often an *extractable* (the chemical that can be forced out of a device or product) investigation is done in conjunction with, or prior to, a *leachables* (the chemicals that migrate from one material matrix into another under normal storage conditions) study in order to get a full profile of the potential hazards of a pharmaceutical product, container closure system, or medical device. This typically incorporates an analysis of *storage stability* under a variety of controlled conditions. If any leachables of concern are noted it may also be necessary to *develop* and *validate methods* to monitor these elements/chemicals over time and across lots. This presentation will provide an example of a case where the product development company did not conduct a full evaluation of extractables from syringe components. After exposure to the drug product, in the pre-filled syringe, discoloration occurred. The study helped identify elemental impurities as the root cause of a syringe discoloration.

4:30 *End of Day One*

Thursday, September 24, 2020, *Eastern Daylight Time*

8:45 *Pharma Ed welcome and opening remarks*

Case Studies in Product Development

9:00

Case Studies in Launching Platforms for Big and Small Pharma

Steven Badelt, Ph.D., Managing Partner, Suttons Creek

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 execution, on getting approvals from the agencies, and solution pathways. Key takeaways include:

- Challenges, case studies from over 50 combination products
- Governance considerations
- What we've learned and implemented into our internal IP
- The common challenges seen in execution
- Integration of concepts from some recent FDA presentations

9:40 **E&L Considerations for Customized Syringe Delivery Systems**

James Scull, Scientific Director, Element Health Sciences

Whilst vendors have done an excellent job of anticipating market needs and developing a range of PFS options, there are occasions when the complexity of the drug product or the route of administration requires a custom solution. This often requires the assembled device to be a combination of parts from multiple vendors. In some cases, parts from non-PFS or non-traditional vendors may need to be incorporated into the design. This approach may be used for prototype devices used in early clinical trials, as the final commercial device would have a more robust design history file. Nonetheless, the early trials may require an E&L evaluation of the custom device based on the patient population or route of administration or both. This case study will explore the E&L consideration of such custom delivery systems in order to meet regulatory requirements.

10:20 ***Morning break & Sponsor Presentations***

10:40 **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.

11:20 **Panel Discussion: Product Development—Meeting Challenges, Seizing Opportunities**

Panelists:

- Steven Badelt, Sutton's Creek
- Howard Drake, Stevanato Group

Discussants:

- The Audience

12:00 ***Lunch Hour. Visit the networking chatroom.***

1:00 **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.

Technology Spotlight—Performance Considerations for PFS & AI: Two Case Studies

1:20 **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.

Critical Issues—Risk Management Across Product Life-Cycles

2:00 **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.

2:40 ***Afternoon break & Sponsor Presentations***

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3:00 **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

3:40 **Tackle Pre-filled Syringe QC with Bouncer**

Joe Barco, Ph.D., Senior Director Marketing, Unchained Labs

Syringe siliconization makes drug injections smoother and easier. Too little silicone, and the device can get jammed up, but too much and silicone can ooze into the drug causing aggregation. Bouncer measures silicone thickness and distribution in minutes so you can ensure the coating is just right. We will discuss how understanding silicone thickness and distribution can improve device manufacturing and the long-term stability of biologic formulations.

4:20 ***Close of Program***

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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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