Pre-filled Syringes & Auto-Injectors Forum 2020
September 23–24, 2020, Philadelphia, PA

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)
- 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!

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Welcome and Opening Remarks
Complimentary Breakfast & Chairperson’s Welcome and Opening Remarks
7:45

Prefilled Syringes in Auto-Injectors—A Brief History and Outlook for the Future
Mathias Romacker, Independent Consultant, Formerly Pfizer
8:20

This presentation will discuss the rationale for using prefilled syringes and how they became the container of choice for fixed dose auto-injectors. The talk will explore why often pharmaceutical companies struggle to align on a perspective on the value of such arrangements; and how a portfolio view can help to find common ground on the value drivers. The presentation will review medicines that have been launched since 2006 in PFS based single use spring driven auto-injectors. Finally, we will look at mega trends across the industry and how they may impact the future PFS and auto-injector landscape.

Drug Delivery Device Technology Spotlight—Challenges and Opportunities in Connected Health
8:55

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.

Biological Drugs Differentiated by Injection Devices: Recent Trends in Auto-Injectors and Connectivity
Robin Hwang, Founder, ICP Consulting
9:35

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 auto-injectors. 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
10:15

Exhibit Viewing & Networking Coffee Break
10:50

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.

Method and Analysis for Assessing Hand Strength Capabilities When Using Pre-filled Syringes
Ed Halpern, Senior Principal Research Engineer, Human Factors, AbbVie

Human Factors Engineering is responsible for providing human capability data as design requirement input, often to ensure that the use of products is within the physical capabilities of intended users. Often, this includes hand strength and hand dexterity data. This presentation summarizes a simulated use study with patients, caregivers and Healthcare Professionals who performed simulated injections with placebo. The results illustrate human injection capabilities, characterized as force over time.

Complimentary Networking Lunch
12:10
Critical Issues—Improving Patient Participation in Clinical Studies

3:45

Broadening Patient Access to Clinical Studies for Self-Administered Medications (PFS and Autoinjector)

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 centric 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.

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

Panelists:
- Bob Laughner, AstraZeneca
- Jason Lipman, Sanofi

Discussants:
- The Audience
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

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.

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 depics 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.
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.

**Exhibit Viewing & Networking Coffee Break**

**2:55 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

**3:35 Syringe Second Source Initiative: A Dual Source Identification to Reduce Supply Risk**

*Nathan Heacock, Product Development Scientist, Glaxo Smith Kline*

Abstract Coming Soon

**4:05 Close of Program**
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Event Dates: September 23 – 24, 2020
Venue/Hotel: Wyndham Philadelphia Historical District
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