Pre-filled Syringes & Auto-Injectors Forum 2020
May 12–13, 2020, Philadelphia, PA

Featuring Lessons Learned & Case Studies From Industry Experts:

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:
Tuesday, May 12, 2020

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

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

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 micro-processor 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.

9:35
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 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.

10:15
Exhibit Viewing & Networking Coffee Break

10:50
Critical Issues—Spotlight on Human Factors in PFS & Auto-Injectors

11:30
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.

12:10
Complimentary Networking Lunch
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 tele-communication 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.

4:25

End of Day One

Wednesday, May 13, 2020

7:45

Complimentary Breakfast

Case Studies in Product Development

8:20

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
10:35 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

11:05 Performance Characterization of Two Different
Autoinjectors

Kevin Duffy, Senior Engineer Consultant,
Eli Lilly & Co.

Autoinjectors provide convenience to patients as an ef-
ficient 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 experimen-
tal study which integrates simultaneous measurements of
force profiles, audible dose confirmation of injection com-
opletion, 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.

11:45 Tale of Two PFS Manufacturing Process
Considerations—Leakage and Clogging

Yuh-Fun Maa, Senior Principal Engineer, Genentech

This presentation covers two pre-filled syringe manu-
facturing 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 re-
lation 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 formul-
ations in minimizing the risk of filling needle clogging
which may deteriorate filling process robustness and po-
tentially affect product quality.

8:55 Development of Platform-based Combination
Products for Self-Injection

Jakob Lange, Senior Director, Delivery
Systems, Ypsomed AG

This presentation will provide an introduction to de-
vices 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

9:30 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 con-
sider, such as delivery methods, design of primary pack-
aging, 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 geomet-
ries and elemental compositions. All these are critical
aspects to carefully evaluate in order to guarantee ef-
fective, 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 de-
sign, testing and process scalability from clinical phase
to commercialization.

10:05 Exhibit Viewing & Networking Coffee Break

10:05 Exhibit Viewing & Networking Coffee Break
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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VENUE INFORMATION:
Event Dates: May 12–13, 2020
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