PharmaED RESOURCES, Inc.

Pre-filled Syringes & Auto-Injectors Forum 2022

December 1–2, La Jolla, CA

Featuring Lessons Learned & Case Studies from Industry Experts

Carolyn Dorgan
Suttons Creek

Paul Upham
Genentech

Michael Song
Takeda

Steve Badelt
Suttons Creek

Alie Janangir
Janssen Pharmaceutical

Jakob Lange
Ypsomed AG

Ajit D'Souza
Kiniksa Pharmaceuticals

Sibgat Ulla
ZebraSci

Paul Reyland
CCL Healthcare

Fubin Wu
GessNet

Katie Falcone
Datwyler

Kevin Hutter
GSK

Larry Atupem
Zeon

Joely Gardner
CSU Fullerton

Robin Hwang
ICP Consulting

Jesper Roested
Subcuject

Anthony Andre
Interface Analysis Assoc.

And Comprehensive Coverage On:

- Understanding the Implications of Recent FDA Guidances for Drug-Device and Biologic-Device Combination Products
- Digital and Connected Health – Smart Device Application for PFS and Auto-injectors
- Bringing Human-Centered Design to Digital and Connected Devices
- Driving Interdisciplinary/Cross Functional Team Collaboration for Successful Complex Device Development
- Applying Safety Engineering to Drug Delivery Medical Devices
- Human Factors—Translating User Research to Actionable Product Specification
- The Intersection of Risk Management and Human Factors in Platform Injection Devices
- How to Successfully Navigate the Human Factors Validation of Combination Drug Products
- Application of Small-Scale Filling Equipment for Biopharm and Small Molecule Products: Case Studies
- From Vial to Autoinjector—2006 to 2022
- Understanding Break-loose & Glide Force Behavior in Prefilled Syringes Systems: Optimizing for Success in Various Patient Populations
- A Glass Alternative: ZEONEX® and ZEONOR® Cyclo Olefin Polymer (COP) for Pre-Filled Syringes
- Best Practices in Manufacturing & Processing
- Control Strategy and Design Transfer for PFS and Auto-Injectors
- Integrated Development and Risk Management Process for Parenteral Products
- And More!

With Representation From:

Suttons Creek, Inc. The Device Team for Pharma · ZEBRASCI COMBINATION PRODUCT EXPERTS · janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson · Genentech A Member of the Roche Group · Takeda · gsk · YPSOMED SELFCARE SOLUTIONS · Subcuject

CCL · KINIKSA · ZEON · DATWYLER · Assurance Case Risk Management GessNet™ · ICP CONSULTING · InterfaceAnalysis ASSOCIATES · CALIFORNIA STATE UNIVERSITY FULLERTON

Contact: Kim Hubbard
khubbard@pharmaedresources.com or call (217) 721-5774

Pre-Filled Syringes & Auto-Injectors Forum 2022
Sponsored By:

Gold Sponsor

Subcuject

Silver Sponsor

CCL

MITSUBISHI GAS CHEMICAL

Event Sponsors

ZEON

Oliver DESIGN

DATWYLER

SYNTEGON
PROCESSING & PACKAGING

EKG Labs
Heartbeat of Analytical Services

CREDENCE MEDSYSTEMS

NOXILIZER™

Boston ANALYTICAL

SMITHERS
INNOVATE WITH CONFIDENCE

Suttons Creek, Inc.
The Device Team for Pharma

Media Sponsors

Drug Development & Delivery

ON drugDELIVERY

Thursday, December 1, 2022

7:00 *Sign-in and Complimentary Breakfast*

7:55

Chairperson Steve Badelt's Welcome & Opening Remarks

Technology Spotlight—Smart Devices and the PFS & AI Landscape

8:00

Digital and Connected Health—Smart Device Application for Pre-filled Syringes & Autoinjectors

Michael Song, PhD, Associate Director of Device Development, Takeda

Digital and connected health technologies are revolutionizing the device development field. This presentation will address several key factors in that ongoing process, including:

- Role of connected PFS and AI in digital health
- Digital connectivity technologies, unique consideration for injectable systems
- Design and development considerations
- Clinical and commercial consideration for connected drug delivery devices

8:40

Bringing Human-Centered Design to Digital and Connected Devices

Paul Upham, Head of Smart Devices, Roche/Genentech

As digital and connected devices become more prevalent as part of a digital ecosystem, the use of human-centered design principles is more important than ever. This presentation will highlight they key considerations for product design and development, manufacturing, quality, regulatory, and commercialization, including the role of behavior design as a critical element for digital solutions used by patients. The presentation will draw on lessons learned from the consumer technology industry and how those methods and tools can be applied to digital health and connected solutions.

Critical Issues in Device Development

9:20

Large Volume Injections: At the Crossroads Between Handheld Devices and Wearables

Jakob Lange, Senior Director Delivery Systems, Ypsomed AG

This presentation will address several critical issues facing any developer of large volume injectables, including:

- Introduction to devices for self-injection with market overview
- Drivers for larger volume injections
- Options for large volumes
- Limitations & opportunities with current approaches
- Possibilities for new developments
- Case study: Study of patient preference for hand-held vs patch

10:00 *Networking Coffee Break*

10:30

Are Companies Ready for Combination Product Digital Transformation?

Dr. Alie Jahangir, Sr. Principal Quality Engineer, Janssen Pharmaceutical

Emergence of digital technologies in various industries have been occurring at an astounding pace over the past decade. As a data-intensive industries, both pharma and medical device, can benefit from this technological transformation and create benefits across their value chains, thereby free up valuable business resources to focus on higher value tasks mainly focused on addressing patients' unmet needs. In essence, the Quality 4.0 provides an effective framework to transition from a compliance-based, reactive, error-prone, and siloed Quality Management System (QMS) to the one that is proactive, integrated, efficient, and most importantly patient centric, thanks to the application of available digital tools, including ML/AI, CM&S, and data analytics. Adoption of this advanced QMS would result in process and systems agility, efficiency, and flexibility, while breaking the silos in product development and validation. FDA and other regulatory bodies have also been quite active to advance digital health priorities both organizationally and from regulatory policy changes to ensure the safety and efficacy of digital technologies, devices, and applications. This presentation will provide the audience with required knowledge to make informed decision about their organization's digital journey, while enabling them to identify technical gaps/opportunities in their current systems and processes.

11:10 **Driving Interdisciplinary/Cross Functional Team Collaboration for Successful Complex Device Development**

Ajit D'Souza, PhD, Director, Combination Product Development, Kiniksa Pharmaceuticals

As healthcare systems increasingly rely on medical care administered at home, the focus on ease of administration, safety, compliance and sustainability is driving the development of increasingly complex drug delivery devices. Formerly mechanical systems are being replaced by software controlled electro-mechanical devices with multiple subsystems. Such complexity often leads to challenges not only in transferring the product specification to subsequent capable manufacturing processes but also in integrating the various subsystems requiring design changes late in the development process. The majority of the problems are encountered at interfaces—contextual, technical and/or organizational. This presentation will discuss barriers to interdisciplinary collaboration and share systems engineering best practices and tools to drive the development teams' understanding of the design, identify challenges early and minimize expensive design changes late in the development phase.

11:50 ***Complimentary Networking Lunch***

1:05 **CCL Healthcare Presentation**

Paul Reyland, Director of Sales, CCL Healthcare

Abstract coming soon

1:25 **Mitsubishi Gas Chemical Presentation**

Speaker to be announced.

Abstract coming soon

1:45 ***Lessons from Integrating the Pharma Industry: Bridging the Gap Between Pharma and Device***

Steven Badelt, PhD, Founder & CEO, Suttons Creek

When a drug company comes together with a device manufacturer to make a combination product, it is vital that each player understands the (very different) perspective of the other. Even more critical is for both players to understand how their integration creates a new perspective, what can be called the "combination product perspective." This presentation will walk you through the hot buttons and best practices from the combination product perspective, and that matter most in your product development, including:

- **What it takes**—What resources and knowledge do you (both pharma and vendor) need to get the job done well (according to regulatory bodies and product users)
- **What it costs**—How investing the right amount of time and money can create higher profit margins in the end
- **What you can do to set yourself up for success**—Learn from our experience and walk away with key considerations, crucial integration points, and best practices

2:25 ***Afternoon Break***

2:55 **From Vial to Autoinjector—2006 to 2022**

Robin Hwang, Founder & Principal, ICP Consulting Corp

It's been over 16 years since the first launch of the autoinjector in the biopharma industry. Since 2005, autoinjector launches have experienced a steady rise. In fact, the trend has accelerated in the past decade and there are currently around 100 commercialized autoinjector products globally in 2022. The device suppliers and biopharma companies as well as the regulators (FDA/EMA) all have learned and adapted the autoinjector combination product development process. This talk provides an overview of this "platform approach" adaptation, enabling a significant reduction of development cost and time. In fact, the platform approach to autoinjectors enables a small biopharma company to reach phase 3 clinical supplies with about $1M in 1 year after the drug product in PFS is established.

3:35 **De-risk Combination Product Commercial Launch by Characterizing Delivery System Through Scientific Technologies and Simulations**

Sibgat Ulla, Associate Director, Combination Product Services, ZebraSci

Abstract coming soon

Panel Discussion—What's Next in Pre-filled Syringes and Autoinjectors?

4:15 **The Next Generation of Devices—A Roundtable Discussion**

Panelists:

- Alie Jahangir, Janssen Pharmaceutical
- Michael Song, Takeda
- Paul Upham, Roche/Genentech

Discussants: The Audience

5:00 ***Happy Hour Mixer***

Join your colleagues in the bar area for some informal networking. Complimentary appetizers provided

Friday, December 2, 2022

7:45 *Complimentary Breakfast*

Critical Issues—Spotlight on Human Factors

8:30 **The Intersection of Risk Management and Human Factors in Platform Injection Devices**

Carolyn Dorgan, Director, Technical Services, Suttons Creek, Inc.

Not all injection devices are created equal, especially when it comes to platform devices. While selection of a platform device can appear as a faster way to market, there are critical implications from a human factors and risk management perspective to consider. Many programs do not perform such analysis until too late in the development process leading to costly program delays. This is becoming increasingly more common when moving therapies from the clinic to the home.

Utilizing risk management tools and Human Factors studies early and often in an iterative manner can greatly reduce the overall development timeline and risk. We will discuss how to incorporate various risk management tools and Human Factors Engineering principals into the combination product development process using an iterative and patient risk focused approach using case studies and real-world examples. When these tools are properly utilized you can avoid costly delays, getting it right the first time.

8:40 **Stop the Madness! How to Successfully Navigate the Human Factors Validation of Combination Drug Products**

Anthony Andre, Director, Interface Analysis Associates, LLC

Pre-filled syringes (PFS) and autoinjectors are easy-to-use delivery systems that are overwhelmingly preferred by end users. With the proper human factors approach, most PFS and Autoinjector products are easy to validate and gain FDA approval if common industry mistakes are avoided. In this presentation I will review the keys to success as well as the paths to failure for most all PFS and autoinjector combination drug products. The presentation will cover regulatory HF strategy, the decision to adopt the validation vs comparative pathway, instructions and labeling, study planning, study execution and how to best communicate your findings and residual risks to the FDA. After this presentation you will never make the same mistakes again!

9:20 **Dos and Don'ts of Human Factors in Each Phase of the Device Lifecycle**

Joely Gardner, PhD, Usability Testing Expert, CSU-Fullerton

When structured properly, human factors research delivers actionable findings that help you identify and reduce risk, facilitate development, and meet regulatory requirements. Usability testing has always been important to the FDA. In the last few years, it has become a non-negotiable requirement and submissions have been returned because of a lack of human factors testing. In this presentation, you'll hear practical tips for incorporating human factors research practices in each phase of the device lifecycle. There will also be very real examples of "do this at your peril" and how to avoid them.

Key takeaways include:

- Examples of Human Factors methodologies at each phase of the device lifecycle
- A model for Identifying needs that are most important to your users so that you can assign priorities for development
- How very early-stage human factors research can identify use-related risks and deliver actionable information to your development team
- The practical differences between formative and summative research
- Ensure compliance with regulatory bodies

10:00 *Morning Networking Break*

Panel Discussion

10:30 **Meeting Human Factors Expectations in Regulatory Submissions—A Roundtable**




Panelists:

- Anthony Andre, Interface Analysis Assoc.
- Carolyn Dorgan, Suttons Creek
- Joely Gardner, CSU-Fullerton
- Kimbery VanCuren, Suttons Creek

Discussants: The Audience

11:10 **Applying Safety Engineering to Drug Delivery Medical Devices**

Fubin Wu, Co-founder, Gessnet Solutions

Safety engineering is a system engineering discipline which assures that engineered systems provide acceptable levels of safety. Medical device safety engineering assures that a medical device behaves safely through its service life in providing the clinical functions per its intended use and benefits as claimed, i.e., the

device does what it should do and does not do what it should not do.

Application of safety engineering can connect the dots proactively and systematically among clinical benefits, primary functions, EPRs, risk management, reliability, V&V, and manufacturing control strategy. Through examples, this presentation will walk through the steps on how to apply safety engineering to the drug delivery devices and illustrate associated benefits to safety, regulatory compliance, costs for development and life cycle maintenance.

11:50 *Complimentary Networking Lunch*

1:00 **User Friendly, Single Use Wearable Autoinjection Innovations**

Jesper Roested, CEO, Subcuject ApS

This presentation will cover two prefilled, single use and user-friendly wearable platform devices:

- A high force, wearable bolus injector, with an osmotic driven actuator – free of electronics and electromechanical parts to support sustainability. Intended for up to 10+ ml
- A wearable, spring-based autoinjector, intended for larger administration volumes while avoiding the challenge of holding an autoinjector steady during injection. For up to 5+ ml

Both devices feature a standard glass cartridge and automatic needle retraction.

1:40 **A Glass Alternative: ZEONEX® and ZEONOR® Cyclo Olefin Polymer (COP) for Pre-Filled Syringes**

Larry Atupem, Business Development Manager, Zeon

While glass containers remain the standard for many pharmaceutical companies to house their life saving medicines, due to potential issues of breakage, delamination, and adsorption, alternatives for this standard have been explored. Polymer based containers have been the other solution, however they also have their unique challenges. Selection of the right polymer is key. This presentation will look at Cyclo Olefin Polymer and its main attributes, highlighting the reasons why COP has been dubbed one of the best glass alternatives in the market for prefilled filled syringes.

- Key Benefits of COP for Medical Devices
- Case Study on Delamination: COP Syringe vs Glass Syringe
- Case Study on Nucleic Acid Adsorption: COP tube vs PP tube
- Case Study on Protein Adsorption/Aggregation and its effect on Immunogenicity

2:20 *Afternoon Break*

2:35 **Understanding Break-loose & Glide Force Behavior in Prefilled Syringes Systems: Optimizing for Success in Various Patient Populations**

Katie Falcone, Scientific Support Manager, Datwyler

Prefilled syringes (PFS) are effective drug-delivery systems that are patient-friendly and conserve drug product. Though these systems offer clear advantages as a drug delivery platform, their designation as combination products offer additional regulatory challenges. As a combination product, the mechanical functionality of the syringe-elastomer system is an important consideration. An element to consider is the break-loose force (BLF) and gliding force (GF) profile. Different combinations of drugs, syringe barrels, and elastomeric components can produce different BLF & GF profiles. Guidelines offered by USP, ISO, and the FDA do not offer a numeric specification for BLF & GF profiles or force maximums. However, the regulatory guidelines encourage investigators to establish specifications based on the needs of their intended patient population. Therefore, drug companies must be diligent in understanding the abilities of the target patient population. Patients suffering from diseases that affect their dexterity, like rheumatoid arthritis (RA), or juvenile patients, whose fine motor skills may be limited, have different optimum BLF & GF profiles.

The importance of a patient-appropriate BLF & GF profile, elastomeric components' contribution to BLF & GF behavior, and the importance of optimization for efficacious drug-delivery will be discussed in this presentation. Audience takeaways include:

- Gain insight in to the challenges faced by pharmaceutical companies when producing a PFS system
- Gain insight into how the interplay between elastomer, barrel and silicone impacts functional behavior like the BLF & GF
- Gain insight into interactions at the elastomer/ barrel interface and discuss elastomeric options that can help to improve consistency with BLF&GF curve

3:15 **Application of Small-Scale Filling Equipment for Biopharm and Small Molecule Products: Case Studies**

Kevin Hutter, Associate Scientist, GSK

Syringe and vial filling of high concentration mAb and small molecule formulations may present several challenges. Considerable development work may be required to develop a clean filling cycle with small-scale or at-scale equipment. However, performing development work using at-scale equipment is not an efficient and cost-effective long-term option due to hectic manufacturing schedules and associated resource needs. Therefore, it is beneficial to have small-scale filling equipment in an R&D facility to reduce manufacturing interruption.

The small-scale filling line can be used to define optimal filling process parameters, support technology transfer, and develop mitigation strategies for ongoing or potential issues with minimal disruption of normal manufacturing operation. Streamlined ways of working without requiring manufacturing scale line time is expected to result in increased efficiency and improved portfolio progression timelines. In this presentation, a few examples of developing processes for filling of mAb and small molecule formulations using a small-scale scale filling equipment will be summarized.

3:55 ***Close of Program***

PharmaED RESOURCES, Inc.

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

About your conference destination:

La Jolla, California, has enchanted generations of travelers. Follow in their footsteps and embark on an adventure like no other with a stay at Sheraton La Jolla Hotel. Famous attractions like Torrey Pines Golf Course, the San Diego Zoo, Balboa Park, LEGOLAND and the USS Midway are all nearby. Visit celebrated academic institutions such as Birch Aquarium and the University of California San Diego. Our La Jolla hotel also places you near local restaurants, breweries, distilleries and shops. If you prefer to relax at our hotel, we offer an oasis filled with palm trees, manicured gardens, cascading waterfalls and tranquil koi ponds. Stay fit in our hotel gym and heated outdoor pool. At night, savor tasty cuisine, inventive cocktails and live entertainment at our two on-site restaurants before you retire to your peaceful accommodations. See why La Jolla is called the "Jewel of San Diego."

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com **Phone:** (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP: _____ COUNTRY CODE: _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

VENUE INFORMATION:

Dates:	December 1–2, 2022
Venue:	Sheraton La Jolla Hotel
Venue Address:	3299 Holiday Court La Jolla, CA 92037
Venue Phone:	1 (858)-453-5500

Please register me for:

Pre-filled Syringes & Auto-Injectors Forum 2022

Early Bird (by October 1st)	$1,695
Standard Registration	$1,895
Call for government, academic, or non-profit discount	

PAYMENT METHOD

CREDIT CARD REGISTRATION:

☐ CREDIT CARD ☐ VISA ☐ MASTERCARD ☐ AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #:

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.