PharmaED RESOURCES, Inc.

Pre-filled Syringes & Autoinjectors 2023

Exploring the Future of Parenteral Combination Products

December 7-8, 2023, La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

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AstraZeneca

Susan Neadle
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CP Consulting Svcs.

James Wabby
Global Head, Reg.
AbbVie

Natalie Abts
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Michael Song
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Co-founder
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Alex Klara
Specialty Materials
Zeon

Karl Hoelper
Director of Smart Packaging
CCL Healthcare

Jeremy Hemingway
Senior Consultant
Stress Engineering Services

Kelly Wedig
Senior Consultant
Suttons Creek

With Comprehensive Coverage On:

- Digital & Connected Healthcare—The Future of Parenteral Combination Products
- Developing Large Volume Parenterals for Challenging Unmet Needs
- EU MDR Tech File Remediation: What Is It and Why You Should Care
- Next Generation Combination Products
- Connected Drug Delivery Devices—Challenges Today and What the Future Holds
- Development of On Body Delivery Systems (OBDS)
- Best Practices in Product Development, including Essential Performance Requirements, Control Strategies, and Lifecycle Management
- Integrating Cybersecurity with Design Controls and Risk Management
- Adapting to How Patients Want to Consume Their Instruction for Use
- Critical Human Factor Considerations for Injection Devices
- Keys to Developing & Implementing an Integrated Risk Management Strategy Across the Product Lifecycle
- Characterization of Container Closure Integrity at Deep Cold Storage Conditions
- Major Trends in the Development of Handheld Autoinjectors
- Innovation and Future Directions of Drug Delivery Device Design and Development
- And More!

With Representation From:

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The Device Team for Pharma

ON drugDELIVERY

Thursday, December 7, 2023

7:00 *Registration Check-in & Complimentary Breakfast*

7:55 *Chairperson Susan Neadle's Welcome and Opening Remarks*

Conference Keynote

8:00 **Disruptive Medicine Innovation: Next Generation Combination Products**

James Wabby, Global Head, Regulatory Affairs (CoE) Emerging Technologies, Combination Products, and Devices, AbbVie, Inc.

Combination products are emerging as innovative medical products due to their contribution to advancing medical care and are thus expected to have major impact in the coming years. Future technologies are most appealing to patients with ongoing medical conditions that require consistent treatment with daily injections or weekly procedures and unmet medical needs. Overall, the successful development of combination products will require great collaboration within the industry to overcome regulatory, clinical, and technical challenges. This presentation will focus on:

- Analyzing latest regulatory expectations and challenges
- Understanding potential future innovation platforms
- Understanding the regulatory challenges and opportunities ahead

Technology Spotlight—Device Design & Connectivity in the Age of Digital Transformation

8:45 **Connected Drug Delivery Devices—Challenges Today and What the Future Holds**

Michael Song, Director of Packaging Design and Development, GlaxoSmithKline

This presentation will review key emerging trends in digital health care, including:

- The role connected drug delivery device plays in clinical and commercial contexts
- Design and development considerations for success
- Unique challenges for single use combination products

Complimentary WIFI sponsored by Ventura SOLUTIONS

9:25 *Morning Networking Break*

Technology Spotlight—On-body Delivery Systems

9:55 **On-Body Delivery Systems (OBDS): Functional, Quality and Usability Considerations**

Sriram Natarajan, Principal Engineer, Janssen Pharmaceuticals

Abstract Coming Soon

10:35 **Integrating Cybersecurity with Design Controls and Risk Management**

Fubin Wu, Co-founder & President, Gessnet

As drug delivery device combination products become increasingly integrated with technologies of connectivity and digital solutions, cybersecurity risk management becomes essential to assure the safety and effectiveness of the combination products. The recently passed Consolidated Appropriations Act of 2023 includes several cybersecurity provisions that require a premarket application to submit information that demonstrates reasonable assurance of cybersecurity throughout the product life cycle. With examples, this presentation will walk through the best practices on how to effectively meet the cybersecurity requirements in parallel with design controls and risk management.

Panel Discussion

11:15 **Digital & Connected Healthcare—The Future of Parenteral Combination Products**

Moderator: Susan Neadle, Combination Products Consulting Services




Panelists:
Michael Song, GSK
James Wabby, AbbVie
Fubin Wu, Gessnet

Discussants:
The Audience

11:45 **Enabling Injectables with RFID**

Karl Hoelper, Director of Smart Packaging and Marketing, CCL Healthcare, a Division of CCL Label

One of the major roadblocks for RFID and NFC in recent years that has prevented their widespread adoption has been the speed limitations on packaging lines, with maximum speeds reaching only 250 items per minute. However, a groundbreaking RFID technology breakthrough from CCL has enabled line speeds of 700 items per minute, ensuring that production remains efficient and on track. This advancement is poised to unlock the potential of RFID and NFC in revolutionizing the Pharmaceutical and Medical device industry. In this brief talk, we will cover several key aspects of RFID, including:

- RFID Line Management
- High Speed Encoding
- Inventory Management
- Dual Frequency RFID/NFC
- Matching GS1 Encoding

12:10 ***Complimentary Lunch, Sponsored by***

CCL

1:20 **A Proactive Approach to Combination Product Development for Successful Commercialization**

Sibgat Ulla, Associate Director, Combination Product Services and Site Lead, BD/ZebraSci

Abstract coming soon

2:00 **Quality Considerations and Assessment of Generic Parenteral Combination Drug Products**

Kai Kwok, Senior Quality Assessor, CDER-FDA

With advancement in complexity and innovation of combination products to advance patient care, more complex drug-device combination products are submitted to the Agency for approval. To promote a complete, high-quality submission of an ANDA, this presentation discusses assessment process, product development studies to demonstrate suitability for use, including performance/functionality, and control strategy and stability testing of prefilled syringes and injectors. This presentation is intended to benefit applicants to obtain ANDA approval with fewer number of assessment cycles, thereby facilitating early access to quality generic drug products for patients.

2:40 **Beyond Design Guidelines: Spring Subject Matter Experts**

Drew Jelgerhuis, Business Development Manager, Scherdel Medtec North America

Many developers and designers in search of expertise will rely on specific design guidelines. Although much value can be derived from these guidelines, the wide range of specialized fields of engineering makes it nearly impossible to contain all the relevant knowledge that a subject matter expert can bring to bear to a design concept. A dedicated team of engineers (mechanical, electrical, manufacturing, process, material, etc.), scientists, software developers, and analysts all focused on one sector of products will bring to bear both the breadth and depth necessary to understand all the technical aspects of the subject at hand. When these subject matter experts are equipped and skilled at the best and most comprehensive software tools they can bring great value to the overall development of a product when engaged as early as possible. Development engineers are constantly trying to understand how their design will perform under various conditions, environments and applications. Simultaneously, project managers are trying to reduce the project's time to market and cut costs to beat the competition. Serving both these aims, simulation services & engineering tools are a great tool with which to test and evaluate designs and thus improve time to market and reduce overall costs before even making a prototype. The benefits that result from numerical simulation are as follows:

- Deviation between simulation and testing is less than 10%
- First-time-right prototypes are made a reality
- Simulation speeds up development times
- Simulation finds better solutions
- Simulation is always faster than trial and error with prototypes
- Simulation provides greater insight
- Simulation costs are investigations in fault prevention
- Co-ordinated use of simulation and testing is the fastest way to new products.

3.00 ***Afternoon Networking Break, Sponsored by***

SCHERDEL medtec

Spotlight on Essential Performance Requirements

3:30

EPR & Testing Insights for Injection Devices

Jennifer L. Riter, Senior Director, Business & Technical Operations, West Pharmaceutical Services, & Susan Neadle, Principal Consultant & President, Combination Products Consulting Services, LLC

Regulations and guidance on Combination Products continue to evolve both domestically and abroad. As the regulatory guidance and expectations around drug device Combination Products continues to develop, the topic of Essential Performance Requirements (EPRs) has been applied to drug device combination products in the United States market. EPRs should be chosen based on a risked based process and documented to show they are appropriate for the specific combination product ap¬plication. This includes addressing risk-based scientific and technological considerations of the combination product system. Understanding how to identify Essential Performance Requirements (EPRs) as well as determining the analytical approach and control strategies for EPRs is critical to the develop¬ment of a combination product. Extractables and leachables analysis of the materials in devices and primary containment systems for combination products is also a key factor and needs to be part of the testing strategy. This presentation will educate and provide examples of common EPRs for several types of injectable delivery systems and testing for extractables and leachables of devices and containment systems as constituents of the combination product. There will be a discussion on the approach that can be taken in identifying risks, analytical testing and characterization.

4:15

Case Study: Characterization of Container Closure Integrity of a Range of Pre-filled Syringe Configurations at Deep Cold Storage Conditions

Duncan Paterson, Senior Director, Device Development, AstraZeneca; Sonia Dragulin-Otto, Senior Scientist, Formulation Sciences, AstraZeneca; and Jeremy Hemingway, Senior Consultant, Stress Engineering Services

CASE STUDY

Storage at lower temperature conditions is necessary for certain drug products due to limited shelf life at 2-8°C. However, storing Pre-filled Syringes at or below -20°C introduces risks to CCI, primarily due to dissimilar mechanical properties of the syringe barrel compared to the elastomeric plunger stopper, and material property shifts near the glass transition temperature of the elastomer. Elastomers have high coefficients of thermal expansion (CTE) and therefore the plunger stopper will tend to shrink more than the barrel (especially with glass barrels) as the temperature of the PFS is lowered. Dissimilar shrinkage of the components reduces the contact pressure between the barrel and plunger stopper and increase the risk of CCI failures. Empirical CCI testing used laser headspace analysis combined with a thermal cycling chamber with

CO2 purge to enable detection of transitory CCI failures (undetectable using more common CCI methods) at frozen storage conditions. Glass and polymer syringes (1mLL and 1mL Std sizes) together with a range of plunger stoppers (coated and uncoated) were evaluated and the CCI testing results compared to in-situ images and theoretical modeling of the container closure sealing interfaces. The characterization techniques, results and conclusions will be discussed, and recommendations for development of a PFS presentation requiring frozen storage shared.

4:55 ***Happy Hour Mixer***

Join your colleagues in the lounge for informal networking. Complimentary appetizers provided.

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The Device Team for Pharma

Friday, December 8, 2023

7:15 ***Complimentary Breakfast, Sponsored by***

ZEON

8:15

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

Alex Klara, Business Development Specialist, Zeon Specialty Materials

Materials selection has become more of a process for pre-filled medical devices as glass is no longer the only choice. ZEON's Zeonex® and Zeonor® cyclo olefin polymer (COP) is an excellent option that allows for advanced, break-resistant syringes, vials and lyophilization containers for protein-based biopharmaceuticals, high viscosity drugs, and contrast media. Our presentation will be an overview of the following:

- Key Benefits of COP for Injection Devices
- Case Study on Delamination: COP Syringe vs Glass Syringe
- Case Study on Protein Adsorption/Aggregation and its effect on Immunogenicity

Complimentary WIFI sponsored by Ventura SOLUTIONS

Spotlight on Large Volume Parenterals

8:45 **Partnering for Success: Increasing ROI for Pharma, Vendors, and CMOs on One Combination Products Case Study**

Steven Badelt, PhD, CEO and Founder, Suttons Creek, Inc.

Suttons Creek has taken seats at 120+ Pharma, Device Vendor, and CMOs combination product team tables over the last 12 years. One outcome holds true no matter the project: the better the collaboration and expertise, the higher the ROI. In this talk, we will answer questions about who needs to talk to whom, about what, and when. We will review the industry's most common missteps, and detail a case study that highlights what it takes for successful partnering internally across functions and also externally with suppliers. You will walk away with:

- A holistic view of a combination product program
- Knowledge of common pitfalls (so you can avoid them!)
- An insider's understanding of how one combination product partnership got to market
- Metrics you can use as a reference point for building your combination product programs
- Practical steps and key considerations for building profitable combination product partnerships

9:25 **What Are the Major Trends in the Development of Handheld Autoinjectors?**

Jakob Lange, Head of Account & Business Development, Vice President, Ypsomed AG

This presentation will cover current trends in the AI market. Key takeaways will include:

· Introduction to autoinjectors and current market overview

· Trend 1: Larger manufacturing volumes & sustainability

· Trend 2: Larger injection volumes

· Trend 3: Digital health & connectivity

· Summary and outlook

10:05 ***Morning Networking Break***

Regulatory Spotlight on Human Factors: The New FDA Guidance & EU MDR Tech File Remediation

10:35 **Updates on the Regulatory Landscape for Human Factors in Combination Product Development**

Natalie Abts, Head of Human Factors Engineering, Genentech

The FDA has recently released their final guidance on applying human factors engineering in the development of combination products, replacing the draft guidance released in 2016. Though the new guidance is substantially different from the draft, the impact to developers is likely to vary based on the maturity of their human factors programs. This presentation will include an overview of the updates to the document, analysis of the content, and the key considerations for developers.

11:15 **EU MDR Tech File Remediation: What Is It and Why You Should Care**

Joely Gardner, PhD, Usability Testing Expert/ Professor, ALKU/Cal State Fullerton

This highly interactive presentation will cover topics such as:

- What exactly is EU MDR?
- What is tech file remediation?
- How does Human Factors in device development differ from Human Factors in tech file remediation?
- How do you plan a business strategy for product portfolio assessment?
- What Human Factors activities are part of tech file review and remediation?

11:55 ***Complimentary Lunch, Sponsored by***

SCHOTT PHARMA

1:00 **A Case Study in the Development of a Large Volume Pre-filled Syringe for Autoinjector Applications**

Daniele Tartini, Business Development Manager—North America, SCHOTT Pharma

Abstract Coming Soon

1:25 **Integrated Risk Management and Controls for Injection Devices**

Susan Neadle, Principal Consultant & President, Combination Products Consulting Services, LLC

This presentation provides a high-level overview of injection device risk management considerations, and then delves more deeply into the topic, including:

- Injection device specific unique risk elements.
- A modular stepwise process for combination product risk management, including key expectations and best practices.
- Considerations for use of Third-Party Suppliers.
- Risk Management for Components/ Constituent Parts not developed under ISO 14971; and
- Platform approach to drive efficiencies in development without compromising the critical proactive consideration of joint use of the differently regulated constituent parts.

2:05 **A Technique for Integrating Risk Management Processes for Combination Product Development**

Kelly Wedig, Senior Consultant, Suttons Creek, Inc.

When pharmaceutical companies partner with external delivery device manufacturers many processes need to be integrated together for the purpose of developing the combination product. One such process is risk management. Together the two parties have to align on several aspects of the risk management process that will be executed for the combination product. Since each group is coming into the collaboration with their own methodologies and constraints it can often be a struggle to reach alignment on the best, most comprehensive approach. In this discussion we will outline a technique for integration of the two risk management processes and discuss the major responsibilities of each function to ensure a streamlined and complete risk management portfolio for the final combination product.

Through examples, this presentation will illustrate how to effectively apply design controls and risk manage- ment for a drug delivery combination product. This in- cludes how to proactively identify the most important function, performance, and safety requirements e.g., primary functions for compliance with ISO 11608, and how to establish a full traceability of design controls and risk management to enable risk-based decision making throughout the product life cycle. The presentation will also illustrate how an organization can benefit from effective design controls and risk management in the selection of drug delivery technology, early engagement with the FDA, and obtaining regulatory approval.

2:45 ***Afternoon Networking Break***

Critical Issues—Cybersecurity & Connected Devices

3:00 **Ambient Temperature Sterilization with Chlorine Dioxide Gas**

Emily Lorcheim, PMP, Project Manager, ClorDiSys Solutions, Inc

Chlorine dioxide gas sterilization is a non-carcinogenic, non-explosive method of sterilization. Chlorine dioxide gas is the closest alternative to ethylene oxide gas in terms of efficacy, but also offers many benefits as compared to it. Chlorine dioxide gas sterilization cycles are dramatically shorter and generally last only 4-6 hours, from pre-conditioning through aeration. It also processes at ambient temperature which is highly favorable for cold-chain or temperature sensitive devices.

Chlorine dioxide sterilization also creates an ease in the cycle itself due to the entire process being conducted in the one single chamber. Items can be loaded into a single sterilization chamber and within it, pre-conditioning, conditioning, exposure, and aeration, all occurs inside. Unlike other common modes of medical device sterilization, chlorine dioxide gas generators have the unique ability to accurately monitor the entire process. Chlorine dioxide gas sterilization cycles can monitor humidity, concentration, dosage, and a host of other parameters. Accurate concentration monitoring allows for parametric release of products.

Chlorine dioxide gas has the ability to effectively sterilize devices in primary, secondary, and tertiary packaging. This includes cellulose materials, which other novel sterilization methodologies cannot sterilize. Overall, the lack of heat generated during the sterilization process, shortened Time Out of Refrigeration, flexibility in packaging allowed, material compatibility, and efficacy prove chlorine dioxide to be the optimal sterilization methodology for pre-filled syringes and autoinjectors.

3:40 ***Close of Program***

PharmaED RESOURCES, Inc.

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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

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VENUE INFORMATION:

Dates:	December 7-8, 2023
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 & Autoinjectors 2023

Standard Registration	$1,895
Early Bird Registration (by October 21)	$1,695
Call for government, academic, or non-profit rate	

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