PharmaED RESOURCES, Inc.

Pre-filled Syringes & Injection Devices 2024

Exploring the Future of Parenteral Combination Products

December 4-5, 2024, La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Subhi Saadeh
Senior Manager
Gilead Sciences

Yenny Webb-Vargas
Principal Statistical Scientist
Genentech

James Wabby
Head, Global Regulatory
AbbVie

Heather Guerin
Global Regulatory Director
Novartis

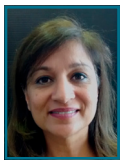
Amir Fakhari
Director, Global Technical Operations
AstraZeneca

Jennifer Riter
VP Analytical Services
Kindeva Drug Delivery

Mike Ulman
Technology Manager
West

Ellie Younger
Principal Engineer
AstraZeneca

Steven Badelt
Executive VP
Suttons Creek



Gurmeet Singh
Sr. Director, Bus. Development
West

Sasha Smiljanic
Director Systems Engineering
Eli Lilly & Co.

Nick Carrara
Assoc. Director, Comb. Products
BD

Fubin Wu
Co-founder
Gessnet

Eric Sugalski
Founder & CTO
Archimedic

Emily Lorcheim
Project Manager
ClorDiSys

Neva Manalil
Human Factors Eng.
Design Science

Max Lerman
Sr. Principal Consultant
Suttons Creek

Paul Reyland
Director of Sales
CCL Healthcare

And Comprehensive Coverage On:

- Disruptive Medicine Innovation: Next Generation of Combination Product Technologies
- Use Related Risk Analyses for Combination Products: A Regulatory Perspective
- A Patient-Centric Approach for Improving the Complaint Intake Process for Combination Products
- Essential Drug Delivery Output (EDDO) is the new Essential Performance Requirement (EPR)
- Large Volume Parenterals and the Changing Paradigm in Drug Delivery
- When Supply Chain Compliance Derails Marketing Plans: A Case Study
- Change Management Across the Product Lifecycle
- Market Trends and Lessons Learned in Combination Products
- A 'Variables' Method for Container Closure Integrity Testing (CCIT): Validation and Novel Statistical Technique
- State of the Art Test Method Development and Validation of Combination Products for Successful Commercial Launch
- Critical Human Factor Considerations for Injection Devices
- Managing Drug and Device Interactions Throughout the Combination Product Lifecycle
- The Use of Surrogate Devices for the Validation of Destructive Test Methods for Combination Products
- Chlorine Dioxide Sterilization of Product Filled Syringes and Autoinjectors
- Innovation and Future Directions of Drug Delivery Device Design and Development
- And More!

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khubbard@pharmaedresources.com or call (217) 721-5774

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MED TECH OUTLOOK

Drug Development & Delivery

Wednesday, December 4, 2024

7:30 *Registration Check-in & Complimentary Breakfast*

8:25 *Chairperson Subhi Saadeh's Welcome and Opening Remarks*

Conference Keynote

8:30 **Disruptive Medicine Innovation: Next Generation Combination Products**

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

Innovative combination products within the precision medicine field are continuing to transform healthcare by utilizing regenerative medicine, genomic, and disruptive innovation technologies to provide patients with curative therapies and precision intervention products at the right time as we move from intervention-based healthcare to preventive and proactive healthcare. However, this will require the industry to integrate strategic partnerships, intellectual property (IP) initiatives, product development approaches, and quality system optimizations into the overall regulatory strategy as the traditional "ways of working" and/or processes will be challenged in developing an innovative combination product.

The Regulatory Landscape—FDA's Recent Guidances on Essential Drug Delivery Outputs & Use Related Risk Analyses

9:15 **Essential Drug Delivery Output (EDDO) is the new Essential Performance Requirement (EPR)**

Jennifer Riter, Vice President of Analytical Services, Kindeva Drug Delivery

In June, the FDA released a draft guidance "Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products" to provide better clarity and definition around what was previously known as Essential Performance Requirements (EPRs). The guidance describes FDA's current thinking and recommendations related to the device design outputs that are essential for establishing and assessing drug delivery performance. The guidance includes devices and combination products that include device constituent parts that are intended for delivery of a human drug and biologics. In the presentation we will navigate the draft guidance and discuss the recommended approach to identifying EDDOs, examples of EDDOs for specific types of devices, and the information and data related to EDDOs that are provided in an application

9:55 *Morning Networking Break*

10:25 **Use Related Risk Analyses for Combination Products: A Regulatory Perspective**

Heather Guerin, Global Program Regulatory Director, Medical Devices, Novartis

The FDA's July 2024 Draft guidance "Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products" provides critical insights into the development and implementation of use-related risk analyses (URRA). This guidance aims to assist industry stakeholders in understanding the purpose and essential components of URRA, which is pivotal in identifying and mitigating potential risks associated with the use of combination products.

This presentation will delve into the key aspects of the draft guidance, including the definition and identification of critical tasks, the evaluation of risk controls, and the alignment with existing FDA guidelines. In addition, the presentation will discuss the Guidance's approach to not submitting Human Factors (HF) validation data under certain conditions, providing a framework for comparative analyses and the use of information from other development programs. Attendees will gain a thorough understanding of the guidance's implications for product development and regulatory submissions, along with practical examples and proposed changes to enhance clarity and compliance.

By exploring the FDA's recommendations and industry feedback, this presentation aims to equip professionals with the knowledge to effectively implement URRA in their product development processes, ultimately contributing to improved patient safety and product performance.

11:05 **The Regulatory Environment Explained: Tackling Harmonization Challenges in Combination Products**

Subhi Saadeh, Senor Manager, Quality, Gilead Sciences

The rise of drug/device combination products is transforming healthcare by merging pharmaceuticals with advanced medical devices, offering innovative treatments. As this market expands, successfully navigating the complex international regulatory landscape is crucial. Different regions have varying frameworks for these products, but global harmonization may create opportunities for quicker approvals and broader market access.

This talk will provide an overview of the current regulatory landscape, highlighting key differences across regions and product types. It will also explore the ongoing efforts toward regulatory harmonization, addressing the challenges that companies face, such as managing differing review standards and expectations.

11:45 *Complimentary Lunch, Sponsored by*

CCL

12:55 **Overcoming Challenges and Avoiding Pitfalls of PFS Labeling**

Paul Reyland, Director of Sales, Western NA, CCL Healthcare

From material selection, storage conditions and the emerging need for connected technologies, this presentation will focus on educating and providing examples of common issues and key aspects that are to be considered. Since 1951, CCL has been partnering with our customers worldwide to provide solutions for all their packaging needs, and this presentation will share that expertise, covering:

- Material, ink, varnish, and adhesive selection
- Specialty packaging designs
- Manufacturing obstacles
- Dual Frequency RFID/NFC advantages

Spotlight on Change Management Across the Product Lifecycle

1:15 **Making Change Management More Efficient**

Ellie Younger, Associate Principal Scientist, AstraZeneca

Every product undergoes changes over its lifecycle. Let's take a moment to reflect on the process and renew our commitment to effective change management. Changes can take a variety of forms, from regulatory standards, supplier changes, response to the market and quality improvements. All of these go through the same Design Controls change process—what can we take away from the process and how can we do better in the future?

This presentation focuses on common pitfalls of technical project teams and give examples of how to improve the practice of managing changes. Many of these will seem basic, but let's use this moment of reflection as a reminder that complex issues may have simple solutions. Additionally, the presentation will go through communication techniques that will help your teams be more successful.

How do we start the process by initiating and assessing changes? What are some best practices to employ while executing a change? What can we do to ensure that changes are effective now and into the future? What do auditors look for when reviewing a change? How do we make change more efficient?

Critical Issues—Supply Chain Compliance

1:55 **When Supply Chain Compliance Derails Marketing Plans: A Case Study**

Dr. Max Lerman, Senior Principal Consultant & Associate Director of Technical Development and Learning, Suttons Creek

Complex and interconnected drug delivery systems face competing motivations across pharmaceutical organizations. Due to that increasing complexity and considering relative areas of expertise, one or more companies are typically involved in designing and manufacturing such systems. Unfortunately, inequitable intentions between organizations can increase development costs and timelines, limit market penetration, and hinder device utility.

To make regulator interactions more predictable, Suttons Creek has worked with clients to compare organizational motives, identify ideal suppliers for design and/or manufacture of each device constituent part, and mitigate risks in existing/new supply chains. In this case study, we discuss the importance of early identification of reliable device-constituent suppliers and the impact the supply chain can have on regulatory success.

We use a series of interactions across the supply chain, starting with project conception and closing with current project status, to illustrate how the compounding effect of ignored and/or misunderstood programmatic risks and suboptimal mitigation led to project roadblocks. This discussion is framed by recent regulatory guidance and interest in supply chains, the shared responsibility of compliance across organizations, and best practices to employ when both selecting and overseeing and suppliers. A retrospective review of the timeline, cost, and regulatory impact and how the program could have been better managed, is presented with opportunities for synergizing development when options become limited due to market and supply pressures.

2:35 *Afternoon Networking Break*

Critical Issues—Innovative Validation Techniques

3:05 **A 'Variables' Method for Container Closure Integrity Testing (CCIT): Validation and Novel Statistical Technique**

Yenny Webb-Vargas, Principal Statistical Scientist, Genentech (Co-authors: Christian Proff, Senior Verification Engineer, Roche, and Irwann Le Bouquin, Device Quality Engineer, Roche)

To comply with USP <1207>, Roche validated a 'variables' method for physical container closure integrity testing (pCCIT) measuring helium leakage from the studied pri-

mary packaging system. To validate this method leveraging USP <1225> and to ensure method robustness, Roche engineered test surrogates that are tested like real primary packaging systems and that are capable of ensuring a repeatable Helium leakage ranging from 10^-9 (mbar*L/s) and above. The test method can be used for vials, syringes, and injection devices. Furthermore, Roche developed a statistical technique that defines a sampling plan that can be used when all units have a helium leakage below the level of validated quantification.

3:45 **The Use of Surrogate Devices for the Validation of Destructive Test Methods for Combination Products**

Mike Ulman, Technology Manager, Packaging/ Delivery Systems, West Pharmaceutical Services

The development of combination products starts with deriving specific Design Input requirements, for the device constituent part, which are based on international standards, guidance documents, formative human factors studies and risk assessments of the combination product's performance. Once the combination product is developed, laboratory-based Design Verification Testing (DVT) must be performed to demonstrate that the device constituent part of that combination product meets the performance requirements that were set in the Design Inputs stage. The analytical methods used to perform Design Verification require analytical method validation. For physical test methods, validation requires assessments of method accuracy (through calibration) and method precision (with a Gauge Repeatability and Reproducibility study). This validation can be performed using actual devices, but for destructive test methods that approach cannot distinguish between poor method precision and part-to-part variation, resulting in exaggerated estimates of measurement uncertainty. However, by designing surrogate devices that look and perform like the devices being tested, but that can be used in a non-destructive fashion, one can perform method validation using those surrogates to demonstrate better method precision and lower measurement uncertainty. Case study examples will be presented.

4:25 **Managing Drug and Device Interactions Throughout the Combination Product Lifecycle**

Fubin Wu, Founder & President, Gessnet

This presentation outlines a comprehensive approach to managing drug-device interactions throughout the product lifecycle. We begin by discussing the importance of managing these interactions for safety, effectiveness, and regulatory compliance, as well as the challenges involved. For example, drug Critical Quality Attributes (CQAs), such as viscosity, can significantly impact device performance, particularly in injectable products where the drug must pass through narrow needle gauges. Conversely, device design and materials may impact drug stability and safety, such as in transdermal patches, where adhesive materials can interact with the drug formulation, affecting its release rate and efficacy. We then explore solutions for managing these interactions using examples based on engineering science, common issues, and lessons learned.

Key elements of design controls, Quality by Design (QbD), and risk management will be examined, including user needs and intended use, Quality Target Product Profile (QTPP), CQAs, Essential Drug Delivery Outputs (EDDOs), Verification and Validation (V&V), Critical Material Attributes (CMAs), risk controls/control strategies, and post-market management. The presentation will highlight the vital role of holistic traceability between design controls and QbD as well as integrated risk management, in managing drug-device interactions.

We will discuss the benefits of this holistic approach for patient-centric design, safety and effectiveness, streamlining combination product development, and post-market management, including issue investigations, change management, and supplier management.

5:05 ***Happy Hour Mixer, Sponsored by***

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Join your colleagues in the lounge for informal networking. Complimentary appetizers & one drink ticket provided, courtesy of Argonaut Manufacturing Services.

Thursday, December 5, 2024

7:30 ***Complimentary Breakfast***

8:25 ***Chairperson Steven Badelt's Welcome & Opening Remarks***

8:30 **Mitigating Risk & Enabling Drug Delivery with a Platform Approach - Innovations & Implications**

Gurmeet Singh, Senior Director, Business Development, Services & Solutions, West Pharmaceutical Services

The global combination products market has seen a tremendous amount of growth driven primarily by the rise in new therapies to address chronic diseases and contributing to a robust drug pipeline driven by biologics. Additionally, the demand for self-administered therapies is pushing the need for new, intuitive, user-driven delivery devices. Novel technologies are also contributing to this growth by offering opportunities to improve drug uptake, reduce pain and improve patient compliance and experience.

As pharmaceutical companies advance new therapies to market, their focus is primarily on the drug or biologic. Early selection of primary packaging components and systems to protect sensitive biologics is critical and can contribute a long-term strategy.

Consideration of the delivery device and the drug-device combination is essential for patient safety and regulatory approval. Without the proper foresight and planning, significant challenges on the device side arise, including complexities related to reliability, human factors, performance testing and process validations. These challenges are often compounded by accelerated schedules after therapeutic efficacy has been demonstrated.

The evolving regulatory landscape requires pharma and biotech companies partner with a true expert who can help them navigate the new regulations successfully.

This presentation with cover:

- Current market trends
- Understanding Impact to Regulations -drug/drug-device
- High value packaging
- Combination Products: Device-Development, Analytical Testing, Manufacturing

8:50 **Market Trends and Lessons Learned in Combination Products**

Steven Badelt, PhD, Executive Vice President and Managing Partner, Suttons Creek—A Division of Tox Strategies

A study of market trends and disclosure of case study-backed best practices that allow combination product developers increased speed to market, return on investment, and market share. Key topics include:

- Current drug delivery market trends
- De-risking delivery device regulatory strategies
- Critical combination product development timelines
- Tips for gaining competitive advantage

Technology Spotlight--Managing Risk in Connected Devices

9.30 **Interoperability-based Risk Management for Connected Combination Products**

Sasha Smiljanic, Director, Systems Engineering, Eli Lilly & Co.

The demand for connected devices continues to grow, as does the expectation for a seamless user experience when it comes to management of personal data. The medical device and combination product space is no different and the industry is moving in this direction.

A key deliverable for any combination product or medical device is a robust risk management file that can be used to support the claim that the overall benefits outweigh the risk. ISO-14971 is used extensively in defining SOPs that apply risk management principles to the product development lifecycle across the industry.

As the industry moves to connected space, the evaluation of risk becomes ever more complex as it needs to be managed across multiple devices and environments (Combination Product + SaMD + Cloud services). An interoperability-based risk management approach can be leveraged to help demonstrate that each device is sufficiently managing risk.

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

10:40 **A Patient-Centric Approach for Improving the Complaint Intake Process for Combination Products**

Amir Fakhari, PhD, Director, Combination Products, Global Technical Operations, AstraZeneca

The complaint management process for combination products is key in addressing patients' concerns during the product's lifecycle. The current limitations and challenges of the complaint management process, such as long processing times and insufficient information for comprehensive complaint analysis including root-cause identification, and risk management activities, are common in the industry.

To overcome these challenges, especially with the increasing complexity of combination products and the growing focus on the patient experience, it is imperative to reevaluate and optimize the processes and systems in place for receiving and addressing product complaints. Utilizing digitalization tools and integrating these into the intake and analysis process to gather comprehensive data at the front end, as part of a patient-centric approach, can help the complaint management team and device subject matter experts to shorten processing times and enhance root-cause identification in investigations.

Panel Discussion

11:20 **The Future of Parenteral Combination Products**
Moderator: Steven Badelt, Suttons Creek




Panelists:

James Wabby, AbbVie

Amir Fakhari, AstraZeneca

Sasha Smiljanic, Eli Lilly & Co.

Discussants:

The Audience

12:00 ***Complimentary Lunch, Sponsored by***

ClorDiSys

1:10 **Chlorine Dioxide Sterilization of Product Filled Syringes and Autoinjectors**

Emily Lorcheim, PMP, Project Manager, Clordisys

Chlorine dioxide gas is an EPA registered sterilant that is non-carcinogenic, non-explosive and can perform sterilization at ambient temperature making it ideal for temperature sensitive or cold chain pre-filled syringes or autoinjectors. Cycle times are also short, ranging from 3-6 hours on average. Not only does this shorten the supply chain, but it is a benefit to cold chain products whose time out of refrigeration is a critical factor. Also to be discussed is the sterilization validation process. Detailed will be case studies that involve material compatibility, residual analysis, biocompatibility, and more. Packaging considerations will also be presented. Unlike other ethylene oxide alternatives, chlorine dioxide does have the ability to sterilize cellulose materials. Sterilization can be completed with product in sterile barrier systems including Tyvek, blister packaging, etc., or even unit cartons or shippers. While contract sterilization is available, the operation of a chlorine dioxide gas sterilization chamber internally will be further explained. This option is feasible because chlorine dioxide is non-explosive at use concentrations and would help reduce sterilization costs, shipping costs, and overall time in the supply chain.

1:30 **Ampoule Filled Syringe (AFS)—The Drug Stability of an Ampoule with the Usability of a Prefilled Syringe**

Eric Sugalski, Founder & CTO, Archimedic

For pharmaceuticals with stability challenges—such as volatility or susceptibility to extractables and leachables (E&L)—ampoules are the gold standard. Their hermetically sealed glass construction minimizes interaction with materials and prevents gas and moisture exchange, ensuring optimal drug stability. However, traditional ampoules pose significant usability hurdles, including the manual breaking process and the need for filter and injection needles to prepare the drug for administration.

Archimedic's Ampoule Filled Syringe (AFS) bridges this gap, offering a breakthrough solution that combines the stability benefits of ampoules with the ease of use found in prefilled syringes. With AFS, a simple squeeze breaks the ampoule and draws the drug into a separate injection chamber via an integrated glass filter. This seamless process eliminates multiple transfer steps while maintaining a form factor familiar to healthcare professionals.

Archimedic will unveil this innovative platform, exploring its design, human factors considerations, and applications across key therapeutic areas. Join us to discover how AFS is redefining drug delivery for complex formulations.

Spotlight on Human Factors

2:10 **Human Factors: Not Just a Checkbox**

Neva Manalil, Human Factors Engineer, Design Science

With advancements in technology and growing options for at-home treatment, patients and their caregivers are more responsible for their care than ever before and play a critical role in determining if drug delivery will be safe and effective. Pre-filled syringes and injection devices are only as good as a user's ability to interpret and activate them. Human Factors engineering, as a discipline, is focused on the potential for errors that can be committed at the interface between the user and the delivery system. In this presentation, you will learn about the requirements for Human Factors for successful regulatory submissions but also why success is best achieved by incorporating Human Factors throughout your development process rather than a final evaluation at the end.

2:50 ***Afternoon Networking Break***

3:05 **Feasibility Assessments: Partnering Early to Mitigate Combination Product Development Risks**

Nick Carrara, Associate Director, Combination Product Development, BD Medical/ Pharmaceutical Systems

Mitigating risk in combination product development is complex. In the development of large volume subcutaneous injection systems these complexities may be intensified. This is true whether you're developing an injection system for the delivery of large or small molecules at any phase of life-cycle management. Areas of uncertainty and risk include drug compatibility, device functionality, usability and overall strategic alignment between pharma and device manufacturers.

Early feasibility assessments conducted in partnership between pharma and experienced device companies offer valuable opportunities to prioritize and study focused areas of potential risk. Structured investigations and testing can be conducted during pharma portfolio planning to provide insights and de-risk potential device options, at the combination product or device platform level.

This presentation will identify a number of key combination product development risks and provide example wearable injector case studies where feasibility assessments were utilized to generate data, helping to inform combination product development and retire risks.

Studies covered may include:

- **Silicone interactions, tungsten residuals, shelf-life and fluid path testing**
- **Container closure integrity, dose accuracy, injection time, and device adhesion**
- **Device usability and human factors considerations**

3:45 ***Close of Program***

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Venue Phone:	1(858)-453-5500

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