PharmaED RESOURCES, Inc.

Combination Products Summit 2024

Product Development, Quality, Safety, & Regulatory Compliance

May 2-3, 2024, Philadelphia PA

Featuring Lessons Learned & Case Studies from Industry Experts

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Sr. Principal Engineer
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Wuxi AppTec

Aaron Sundman
Bus. Development Leader
CCL eAgile, Inc.

And Comprehensive Coverage On:

- The 2024 FDA QMSR and Combination Products cGMPs
- A Path to Approval—The Regulatory Journey of a Combination Product
- Combination Products—Digital Health & Other Updates
- Combination Product Platform Development—Considerations & Strategic Approaches
- Achieving Regulatory Success in Targeted Delivery of Cell & Gene Therapies
- Considerations for Wearable Injectors for Large Volume Delivery
- Enabling Autoinjector Technologies for Delivery of Challenging Applications, Including Long-acting Injectables and Biotherapies
- Is the Delivery Device Value Add? Approaches to Developing the Combination Product Business Case
- The Changing Landscape of Computational Model and Simulation Generated Data as Regulatory Evidence
- Making Change Management More Efficient
- Material Qualification and Control for Combination Products
- Best Practices for Developing Use-related Risk Analyses
- How to Maintain a Clear Track of Safety, Effectiveness, and Compliance
- Analytical Testing Strategy and Approach for Combination Products
- Best Practices in Product Development, including Essential Performance Requirements, Control Strategies, and Lifecycle Management
- And More!

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Thursday, May 2, 2024

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

8:00 *Chairperson Susan Neadle's Welcome and Opening Remarks*

Regulatory Spotlight—Quality Systems & Cell & Gene Therapies

8:05 **The 2024 FDA QMSR and Combination Products cGMPs**

Susan Neadle, Principal & President, Combination Product Consulting Services, LLC

The FDA's Quality System Regulations for medical devices have been in effect since June 1997. On January 31, 2024, the US FDA issued a major update to this regulation. In so doing, they have re-named it the "Quality Management System Regulation" (QMSR), and worked towards harmonizing their expectations with ISO 13485:2016. In this presentation we will review what's new, what's changed, and what's stayed the same in these regulations. We will also review associated impacts to 21 CFR Part 4 (Combination Product cGMPs).

8:45 **Achieving Regulatory Success in Targeted Delivery of Cell & Gene Therapies**

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

Drug preparation and delivery devices (commonly components of Combination Products) are more frequently being leveraged in cell and gene therapy programs as these promising therapies move from pre-clinical to clinical and even commercial phases. However, cell and gene therapies create some unique considerations when it comes to developing and selecting the appropriate devices to deliver these therapies. Many companies are finding difficult development challenges given the specific constraints associated with the manufacture, stability, preparation, and administration of these therapies. In this presentation we will look at the evolution of devices used to prepare and administer cell and gene therapies, the available landscape of delivery devices, and where gaps may exist. We will also walk through the practical application of what to consider when selecting devices, creating design inputs, identifying essential performance requirements and how that should feed into risk management programs and, ultimately, regulatory submissions for these technologies.

9:25 **Driving Efficiency in Combination Product Development: Harnessing the Benefits of Platform Drug-Delivery Devices**

Mahendran Ravichandran, Director, R&D Combination Product Development, AbbVie

This presentation provides an overview of the work involved in identifying and establishing Platform Drug-Delivery Devices. It explains the concept of a drug delivery "platform" and outlines the process of implementing a platform approach. The presentation highlights the benefits of using a platform strategy, showing how it can enhance various elements of product development. The presentation delineates the attributes of drug delivery platforms and distinguishes "A Platform" from "Re-use". A case study of a platform is presented, demonstrating how the platform approach has led to a reduction in development timelines.

10:05 *Networking Coffee Break*

Critical Issues—Digital Health Technologies in Regulatory Perspective

10:35 **Combination Products—Digital Health & Other Updates**

Kristina Lauritsen, Combination Product Policy Advisor & Product Jurisdiction Officer, FDA-CDER

Abstract Coming Soon

11:20 **Shifting Paradigms: Computational Modeling and Simulation Data as Regulatory Evidence in Medical Devices**

Payman Afshari, Senior Principal Engineer, DePuy Synthes Johnson and Johnson

In the realm of medical device regulation, the integration of computational modeling and simulation. aka in silico is revolutionizing the evidence generation landscape. This talk explores the evolving role of in silico generated data as regulatory evidence in the context of devices. We will explore the risk informed framework that governs the process of assessing this type of data, emphasizing the need for robust validation, verification and uncertainty quantification. Additionally this talk aims to provide insights into the global effort to harmonize methods embracing alternative sources of evidence.

12:00 *Complimentary Lunch, sponsored by*

CCL

1:05 **Enabling Injectables with RFID**

Aaron Sundman, Business Development Leader, CCL eAgile, Inc.

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:

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

Technology Spotlight— Key Considerations for Device & Platform Development

1:25 **Considerations for Wearable Injectors for Large Volume Delivery**

Sriram Natarajan, Senior Manager, Johnson & Johnson

Wearable injectors are being developed as an option for larger volume delivery of drugs and biologics. As companies go through the selection and design & development of these, some of the salient points to consider include Applicable standards and regulations, Design Requirements, user preferences and Manufacturability. This talk will provide an overview of these aspects.

2:05 **Combination Product Platform Development— Considerations & Strategic Approaches**

Michael Song, Director, Drug Product Development, Moderna

Abstract Coming Soon

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

3:15 **Enabling Autoinjector Technologies for Delivery of Challenging Applications, Including Long-acting Injectables and Biotherapies**

Asmita Khanolkar, Senior Director, Cambridge Pharma, SMC Ltd.

There is a rising need for enabling drug delivery technology platforms that address delivery solutions for novel therapies. As novel applications are continually requiring higher dose, concentration, volume and viscosity requirements, the need for high- pressure container systems, enabling mechanisms and patient-centric design features are evident. The drug delivery process development entails many nuances of optimization around the drug, the device and the patient interface. The talk will cover some unique methodologies to assess the formulation needs, patient needs and technology solutions to provide a potential solution for the technically challenging delivery needs for Long- Acting Injectables and Biotherapies.

3:55 **Is the Delivery Device Value Add? Approaches to Developing the Combination Product Business Case**

Leilei Zhang, Associate Principal Scientist, Merck

One trend in the Pharma industry has been engaging the case for a combination product more often and earlier in the development cycle. In addition to the benefit the combination product could bring (e.g., ease of use; addressing an unmet therapeutic need, etc.), sometimes it also means more complex development and higher capital investment. The question is then whether the delivery device adds value and how that value overcomes the additional cost and potential longer timeline to launch. In this presentation, we will discuss how to incorporate a business case framework earlier into the program, creating a device-centric business case for development. The presentation will examine quantitative and qualitative analyses of device selection, and will also cover about how to initiate combination product development while refining the business case, utilizing a clear decision tree to make go/no go decisions.

Day One Roundtable Discussion

4:35 **Combination Product Development—Avoiding Regulatory Hang-ups**

Moderator: Susan Neadle, Combination Product Consulting





Panelists:

Carolyn Dorgan, Suttons Creek, Inc.

Mahendran Ravichandran, AbbVie

Sriram Natarajan, Johnson & Johnson

Michael Song, Moderna

Discussants:

The Audience

5:15 ***Happy Hour Mixer***

Join us in the hotel bar to relax, unwind, and informally network. Complimentary appetizers provided.

Friday, May 3, 2024

7:00 ***Complimentary Breakfast***

Critical Issues—Material Qualification and Lifecycle Management

8:00 **Beyond Checklists: Material Qualification and Control for Combination Products**

Subhi Saadeh, Senior Manager, Quality, Gilead Sciences

This session delves into the crucial domain of material qualification for combination products. One size fits all material qualification processes are insufficient in demonstrating compliance on the one hand, and overly burdensome on the other. Recognizing the pivotal role of material integrity in drug/device manufacturing, the session aims to provide an understanding of contemporary challenges and innovative solutions. Subhi will explore regulatory expectations, risk assessment strategies, and methodologies for material qualification and control from other industries, fostering a nuanced discussion on ensuring product quality and compliance. Attendees should expect to gain valuable insights into best practices, emerging trends, and the evolving landscape of material control for combination products.

8:40 **Making Change Management More Efficient**

Ellie Younger, Assoc. Principal Engineer, Combination Products, 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?

9:20 **Advancing Combination Product Development: Connect the Dots from the Outset and Maintain a Clear Track of Safety, Effectiveness, and Compliance**

Fubin Wu, Co-founder, Gessnet

The journey to successful combination product development often encounters challenges that can significantly delay time to market. To navigate these complexities, it is imperative to establish a comprehensive understanding of safety, effectiveness, and compliance from the outset and maintain a focused trajectory throughout the development process.

This presentation introduces a strategic approach that transcends conventional methods, emphasizing holistic integration of these critical aspects at every stage of product development. We will explore common pitfalls that can derail projects, including inadequate or incomplete performance or safety requirements (or their verification and validation evidence), challenges in maintaining design control and risk management-traceability and managing design changes, difficulties in generating comprehensive documentation needed for regulatory submissions.

Through examples and innovative management tools, we will demonstrate the efficacy of a proactive and integrated approach in overcoming these challenges. We will share valuable insights and practical tools on how to

streamline the development process while ensuring that the combination products are safe, effective, and reach the market faster.

10:00 *Morning Networking & Coffee Break*

Spotlight on Human Factors

10:30 **Best Practices for Developing Use-related Risk Analyses and How to Avoid Unnecessary Headaches**

Jennifer Soosaar, Director, Human Factors Practice, Core Human Factors, Inc.

The objective of human factors as it relates to combination products is to support the design of safe and effective drug delivery devices through the application of knowledge about human behavior, the user attributes of the end users, and the potential impact of the intended use environments. The use-related risk analysis itself enables the team to gather that knowledge and create a product that reduces the risks to the end user and supports safe and effective use of the product. I will discuss how the team you already have, including formulation, device engineers, clinical, and human factors experts, among others, can work together to create these foundational documents and mitigate risk from the start. Use-related risk analyses that are not complete indicate that the product and its safety profile are unknown, whereas a complete use-related risk analysis supports you in developing, validating, and marketing a successful product, by ensuring successful mitigations are identified. Throughout I will provide some examples of what to do and not to do in your journey.

11:10 **Obesity: Challenges & Opportunities from Different Perspectives**

Reto Falk, Director, Business Development, Ypsomed AG

We will discuss the epidemic history and future of Obesity, have a look at the treatment revolution and its implication for the combination product industry. Finally, we will assess the sustainability aspect and the expectations of everyone involved.

11:50 **Delivery of Small-molecule Drugs Via On-body Infusor—Clinical Study Results**

Sabine Websky, Head of Medical Affairs & Applied Technologies, Gerresheimer

The subcutaneous route of drug administration is increasingly popular, particularly self-administration, due to the high costs associated with intravenous administration and the patient advantages of therapy in a home-care setting. This presentation looks at the advantages of subcutaneous delivery compared to intravenous administration. It further discusses the effectiveness of subcutaneous delivery of small molecule drugs via an on-body infusor. Evidence will be presented from clinical studies of a novel furosemide formulation delivered subcutaneously via an on-body patch infusor developed by Gerresheimer.

12:10 *Complimentary Lunch, Sponsored by*

gerresheimer

Critical Issues—Ensuring Safety & Compliance in Combination Products

1:10 **A Path to Approval—The Regulatory Journey of a Combination Product**

Sandi Schaible, Senior Director of Analytical Chemistry & Toxicology, WuXi AppTec

US regulatory approval is rarely smooth sailing for any medical product and for combination products the journey can be filled with unexpected detours if you are not properly prepared. Understanding the regulatory landscape before you develop your test plan can get you to your destination on time. We will walk through:

- Why understanding the primary mode of action is important
- How a presub meeting can set you on a clear path
- What are the differences between USP and ISO methods when it comes to Extractable/Leachable testing
- When to apply USP<1663>/USP<1664> and/or ISO 10993 parts 17 and 18 in your test plan

Finally, we will navigate a combination product case study and explore some of the hidden pitfalls encountered during the journey.

1:50 **Analytical Testing Strategy and Approach for Combination Products**

Jennifer Riter, Vice President and Global Head of Analytical Business Unit, Kindeva Drug Delivery

With the evolution of combination products along with the complex interactions with packaging components and delivery systems, it is critical to understand the compatibility and performance of the packaging and delivery systems for the successful development of a combination product. Applying a systematic approach and strategy for the constituent parts as well as the system qualification is critical in ensuring product quality. It is important to understand the physical, functional and chemical compatibility of these components and systems. There are several key areas to assess during development which includes performance, extractables and leachables and container closure integrity (CCI). There are also several techniques to consider when assessing and qualifying the containment system as well as the delivery system. This presentation will educate and provide examples of an analytical strategy and approach for combination products.

2:30 ***Afternoon Networking Break***

2:40 **Post-Market Strategies/Lifecycle Management of Co-packaged Drug/Device Combinations**

Lauren Tiller, Senior Regulatory Affairs Specialist, West Pharmaceutical Services

Post-market surveillance, reporting and life cycle management of drug products are vital to the safety of patients as these activities allow for long-term monitoring of drug effects . When a device is co-packaged with a drug, the device manufacturer must also follow thorough post-marketing activities and maintain a systematic lifecycle management process to ensure the device is safe and effective as a stand-alone device and as a co-packaged product. In this presentation, we will focus on the device and discuss key post-market strategies and lifecycle management responsibilities of the device manufacturer where their devices are co-packaged as a Drug/Device combination in the United States and other countries.

3:20 **Drug-Device Interactions–Choosing the Appropriate Delivery Mechanism and Best Testing Practices to Reduce Particulate Matter in Combination Products**

Jorge Capurro, Director, Drug Delivery, Archimedic

One of the most important safety and performance endpoints for injectable combination products is to meet adequate particulate matter levels as specified in the USP and ISO standards, as applicable. Issues related to elevated particulate matter are sometimes found late in the development effort which can significantly impact timelines and budget; thus, leading to the cancelation of device development projects and even clinical trials. This presentation will examine a process that can be implemented to mitigate potential issues related to particulate matter prior to the significant investment in device development efforts. Insights will be provided on how to choose the appropriate delivery mechanism depending on drug product properties and best practices for choosing the right test method for measuring particulate counts.

Closing Discussion Forum

4:00 **The FDA's Coming Guidance for Essential Performance Requirements—What You Need to Know, & Other Pressing Matters**

Moderator: Susan Neadle, Combination Products Consulting

Discussants: The Audience

4:40 ***Close of Program***

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Venue Phone:	215-923-8660

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