PharmaED RESOURCES, Inc.

Combination Products Virtual Summit 2021

Product Development, Quality, Safety, & Regulatory Compliance

October 26–27, 2021, Online EDT

Featuring Lessons Learned & Case Studies from Industry Experts

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Ypsomed AG

Suzette Roan
Associate VP
Sanofi

Susan Neadle
Exec. Director
Amgen

Khaudeja Bano
Head of CP & Device Safety
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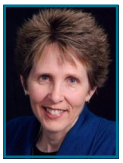

Cheryl Stults
Principal
C & M Consulting

And Comprehensive Coverage On:

- Meeting Regulatory Requirements in an Evolving Global Landscape
- Mapping Procedures for Post-approval Device Changes: Implications for Combination Products
- Best Practices in Product Development, including Essential Performance Requirements, Control Strategies, and Lifecycle Management
- Keys to Developing & Implementing an Integrated Risk Management Strategy Across the Product Lifecycle
- Emerging Platform Technologies-Challenges and Opportunities
- Preparing for the Digitalization Trend in Combination Product Use and Design
- Leveraging Human Factors Engineering in Digital, Connected Health and Drug/Biologic Applications
- PMSR-Meeting the Challenges of the New Post-market Safety Requirements for Constituent Parts
- Smart Devices as Combination Products: Design and Regulatory Challenges
- Innovation and Future Directions of Drug Delivery Device Design and Development
- Development of On Body Delivery Systems (OBDS)
- The Future of Device Global Supply Chain After the Covid Pandemic: Are We Prepared?
- And More!

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Tuesday, October 26, 2021

8:30 

Chairperson's Welcome and Opening Remarks

Key Regulatory Considerations for Combination Products in the Age of COVID

8:35 **Regulatory Considerations for Device Changes across the Product Lifecycle: Implications for Combination Products**

Suzette Roan, Senior Director, Regulatory Devices at Sanofi

Changes are bound to happen during the lifecycle of a combination product and this session will provide regulatory considerations for changes to the combination product and device constituent part which occur during development and in the commercial setting. From the point that the combination product is used in pivotal or registration clinical studies, the potential impacts to the regulatory dossiers and to the development program as a whole need to be considered when there are changes. Changes should be assessed individually and in aggregate to understand the potential impacts to design, performance, materials, manufacturing processes, labeling and user interface. This session will include a discussion on strategies to address changes, including an overview of how approaches outlined in ISO 20069, *Guidance for assessment and evaluation of changes to drug delivery systems*, can be utilized to plan, assess and evaluate combination product changes. At initial registration, it is important to be able to tell the history of the product from the point that the combination product was used in the clinic through to the product that will be commercialized. Smart planning during the initial submission preparation can enable streamlined post-approval changes. This session will provide considerations related to submission content and utilization of regulatory tools, such as those outlined in ICH Q12 and the recent FDA ICH Q12 Implementation Considerations Draft Guidance.

9:20 **Update and Status of Revisions to ISO Drug Delivery Standards**

Lee Leichter, President, P/L Biomedical

Standards play a significant role in the design and quality of products used for the delivery of drugs. The ISO Technical Committee (TC) 84 has been working on substantial revisions to the ISO 11608- series of standards for almost 5 years. In the past, these standards have been the basis for assessing the design of many drug delivery products, such as injection pens and auto-injectors. Major updates to the entire series are planned to be issued as Final Draft International Standards (FDIS) for a final vote this year. The approved versions will be published late this year or early in 2022.

The changes include a separate part addressing On-Body Delivery Systems, an expansion of the cartridge standard to include requirements for unfilled reservoirs and fluid paths, a major revision of the electronic injector standard to include the use of electronics for delivery and other function and more closely aligning to IEC 600601-1 as well as many other significant changes.

In parallel, two new standards have been approved to be developed; one addressing Needle Based Delivery systems intended for pediatric use and another New Work Item (NWI) to address reliability of these systems.

The session will provide insight to the changes that are proposed and the impact on the development of current and future drug delivery products.

10:05 *Morning Break*

10:15 **EU-MDR Implementation for Pharm Centric Combination Products**

Amit Khanolkar, Senior Director, Combination Products & Devices, Janssen Pharmaceuticals

The applicability of the Europe Union Medical Device Regulation 2017/745 (EU-MDR) to Drug-Device Combination Products in general has elicited serious debate within the industry. While the EU-MDR has brought clarity to several areas over the Medical Device Directives 83/42/EEC, there is still significant room for interpretation for manufacturers operating within the framework of the Medicinal Product Directives 2001/83/EC (MPD). Several articles within the EU-MDR outline requirements that are overlapping or similar in intent to requirements in MPD. Industry associations and trade groups have published position papers while requesting the heath authorities to provide clarifications. This presentation provides an overview of the relevant and applicable articles of the MDR for a pharmaceutical organization. The strategy adopted for demonstrating compliance leverages the existing MPD based Quality Management System with appropriate updates to comply with requirements for Combination Products.

11:00 *A Brief Message from our Sponsors*

Roundtable Discussion

11:05 **The Changing Regulatory Landscape for Combination Products**

Moderator: Alie Jahangir, Janssen Pharmaceuticals




Panelists:

- Amit Khanolkar, Janssen Pharmaceuticals
- Susan Neadle, Amgen
- Suzette Roan, Sanofi

Discussants: The Audience

11:50 *Lunch Hour*

Technology Spotlight—Digitilization & the Future of Combination Product Development

12:50 **The Impact of Computation Modeling & Simulation (CM&S) to Transform Combination Product Industry**

Alie Jahangir, PhD, Senior Principal Engineer, Combination Product & Emerging Technologies, Janssen Pharmaceuticals

With world's leading regulatory agencies recognizing the Computational Modeling and Simulation (CM&S) as the fourth paradigm of evidence generation, medical device and combination product industries are on the verge of major digital transformation. Over the past three decades, automotive, aerospace and consumer goods industries have modernized their product development and manufacturing landscape by incorporating advanced CM&S as a standard practice to support the design and the de-risking of new products, scale manufacturing and keeping up with evolving demands. While this digital transformation in combination product may take several forms, the simplest and most common would be to simulate a "platform" drug delivery device under variety of conditions that mimic a certain set of the clinical or use environment to investigate some aspect of the device performance. Furthermore, advanced CM&S capabilities provide the ability to simulate behavior of the various individual components as well as the system before implementation is considered. Specifically, the CM&S may be leveraged to predict how key design parameters (i.e. injection time, injection force, shear stress, etc.) affect the overall performance of an injection device (e.g., autoinjector), bringing benefits in terms of reduced development time, more robust and adaptable designs, while reducing product cost. Finally, an overview of quality and regulatory challenges associated with CM&S will be discussed in this talk.

1:35 *A Brief Message from our Sponsors*

1:40 **Next Generation of Biologic Therapeutics Delivery—Pathways to Digital Medicines in Biopharma**

Ramin Rafiei, Co-founder & Partner, Reformulate Health, & Timothy Aungst, PharmD, Associate Professor, MCPHS University

The convergence of Eroom, Moore and Metcalf's laws are pushing biopharma's laboratory into the real world and accelerating the adoption of real-world evidence across the drug value chain. Coupling new touch points for patient data collection with artificial intelligence (AI) models, the efficiency of pipeline therapeutics is increasing, while enabling the personalized interventions that improve their real-world effectiveness. We see this today in the digital biomarkers collected from next generation biologic delivery devices, which exemplify a new category of superior real-world evidence on adherence, safety signals and patient health behaviors.

Realizing the full potential of these digital medicine products requires shifts in organizational culture and product development lifecycles, flanked by novel go-to-market strategies which we foresee will diverge from conventional models. This talk considers the digital health readiness of the current US biopharmaceutical industry and establishes a framework for realizing validated AI-enabled digital biologic therapeutics.

2:25 *Afternoon Break*

2:35 **Challenges with Material Qualification for Combination Products**

Cheryl LM Stults, PhD, Principal, C & M Technical Consulting, LLC

A medical device may also serve as a packaging/delivery system for a drug-device combination product. As such both device and packaging requirements must be met. Material qualification generally involves satisfying requirements for functionality, safety, compatibility and protection. There are gaps and overlaps in application of multiple standards to medical devices that are also packaging/delivery systems. As ISO standards, USP chapters, regulations and guidances are constantly changing it is challenging to develop qualification plans to meet regulatory authority expectations. This talk will review current regulations and standards as applied in specific case studies for the purpose of illustrating the challenges and streamlined approaches to evaluation and testing.

3:20 *A Brief Message from our Sponsors*

Technology Spotlight—Biodegradable Polymers: Options for Combination Product Development

3:25 **Biodegradable Polymers in Drug Delivery Reconsidered**

Gregory Grover, Chief Technical Officer, Contraline, Inc.

Abstract Coming Soon

4:10 *End of Day One*

Wednesday, October 27, 2021

8:30 *Chairperson's Welcome*

Critical Issues—Recasting Organizational Culture & Product Governance for Combination Product Success

8:35 **Becoming Combination Product "Friendly": An Organization's Journey**

Khaudeja Bano, MD, Executive Medical Director, Combination Product Safety Head, Amgen

Each organization has its own challenges to become combination product ready. In light of the evolving regulatory landscape in the combination product space, changes to many dimensions of an organization need to occur. The biggest of all is a change in culture and mindset.

Is your organization ready for this paradigm shift? In this presentation we will explore areas that need to evolve to maximize success in the Combination Product universe. We will discuss some best practices and various organizational models, along with the associated pros/cons of each, and highlight the key organizing principles that should guide any Combination Product across its lifecycle.

9:20 **Combination Products: A Risk-based Approach**

Susan Neadle, Executive Director, Regulatory Affairs, Amgen

Risk Management serves as a framework for combination product development and pre-market pathways, through post market lifecycle management. In this talk we will review that combination products risk management construct, recognizing consistent aspects that apply in our fast-evolving combination products global regulatory environment. We will highlight examples and best practices in Design Controls, Human Factors, Platform Approaches, Combined Use applications, Purchasing Controls, and EPRs in the context of risk control strategies.

10:05 *A Brief Message from our Sponsors/Morning Break*

10:20 **Understanding the Essential Performance Requirements Connection to Control Strategy**

Jennifer Riter, Senior Director, Business & Technical Operations, West Pharmaceutical Services

Essential Performance Requirements (EPRs) is a relatively new term applied to drug device combination products. EPRs are to have clinical relevance and relate directly to drug quality and patient safety. Even through the lens of a risk assessment, the determination of EPRs can have ambiguity in interpretation.

This presentation will educate and provide examples of EPRs for various types of injectable delivery systems. In addition, the understanding of controls to minimize risks and variability associated with these EPRs is critical to satisfy regulatory agencies and meet patient safety requirements. The understanding of these controls and relationship to the EPRs will also be discussed.

Roundtable Discussion

11:05 **Product Governance & Organizational Culture—Are You Combination Product Ready?**

Moderator: Alie Jahangir, Janssen Pharmaceuticals




Panelists:

- Khaudeja Bano, Amgen
- Jennifer Riter, West
- Susan Neadle, Amgen

Discussants:

The Audience

11:50 *Lunch Hour*

Spotlight on Sustainability & Human Factors in Device Engineering & Manufacture

12:50 **Sustainable Approaches for Self-injection Devices: A Case Study in the YpsoMate Zero Autoinjector**

Jakob Lange, Senior Director, Delivery Systems, Ypsomed AG

This presentation will focus on sustainability practices in product design and manufacturing. Key topics covered will include:

- Introduction to devices for self-injection with market overview
- Approaches to sustainability, examples from industry
- Steps & tools for lifecycle assessments
- Case study: The YpsoMate Zero

1:35 *A Brief Message from our Sponsors*

1:40 **Human-Centered Design of the Next Generation Diabetes Self-management Technologies**

Farzan Sasangohar, Assistant Professor, Wm. Michael Barnes '64 Department of Industrial and Systems Engineering, Texas A&M University

Telemedicine, which involves the use of telecommunication technologies to provide medical care remotely, has shown benefits such as improving access to health-

care, facilitating chronic diseases care management, and improving patient data availability in electronic health records. Despite all these benefits, there are still challenges that need to be addressed to achieve an effective implementation of telemedicine technologies. Understanding the human factors such as readiness to adopt, acceptance, and impact of telemedicine integration on clinical workflow is especially important for successful long-term adoption. A series of studies were conducted to utilize human-centered methodology to inform the design and evaluation of revolutionary diabetes and hypertension self-management technologies. Through these convergent projects, a model called System Adoption and Integration of New Telehealth Systems (SAINTS) was developed to capture elements required for successful integration of telehealth throughout its lifecycle.

2:25 ***A Brief Message from our Sponsors/Afternoon Break***

2:35

Effectively Integrating Human Factors into Combination Product Development

Angela Muriset, Research Director, and Ashley Sutherland, Sr. Research Manager, Design Science

Human factors is now widely accepted as a critical input for effective combination product development. However, organizations vary in how they approach integrating human factors into their overall development efforts. Relevant regulatory guidance and industry standards have helped establish expectations, but can lead to a non-integrated human factors approach when implemented. This talk will focus on the benefits of an integrated human factors approach, common challenges to achieving an integrated human factors approach, and suggestions for how to overcome these challenges.

3:20 ***End of Program***

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In the Age of COVID, the Show Must Go Online

In response to overwhelming audience and speaker feedback, and in view of the current health and safety concerns involving the novel coronavirus COVID-19, we're taking our events online (at least for the foreseeable future; we do hope to see you again soon in person when all this is over!) **Combination Products Virtual Summit 2021** is an entirely online event, complete with insightful presentations from leading researchers, 1:1 networking opportunities, live question & answer sessions, and sponsored informational presentations that highlight how vendors are tackling some of the key issues facing the Combination Products market. Just sit back and enjoy this online learning experience from the safety and comfort of your home or office. Missed a session or two? No worries—the full program will be archived and available for post-conference viewing and download.

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