PharmaED RESOURCES, Inc.

Combination Products Summit 2023

Product Development, Quality, Safety, & Regulatory Compliance

May 16-17, 2023, Philadelphia PA

Featuring Lessons Learned & Case Studies from Industry Experts

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Kinsuk Shah
Director, Device Dev
Viridian Therapeutics

Sriram Natarajan
Sr. Engineer
J&J

Karl Hoelper
Director of Smart Packaging
CCL Healthcare

Reza Abedian
Senior Medical Affairs Manager
Gerresheimer

And Comprehensive Coverage On:

- Integral Device Requirements for EU Clinical Studies
- Developing Combination Products for Challenging Unmet Needs
- Development of On Body Delivery Systems (OBDS)
- Best Practices in Product Development, including Essential Performance Requirements, Control Strategies, and Lifecycle Management
- Combination Product Early Development: Technical, Quality & Clinical Considerations
- Keys to Developing & Implementing an Integrated Risk Management Strategy Across the Product Lifecycle
- Integration Of Next Generation Drug Device Combination Products with Decentralized Care Pathways and Future Clinical Research
- 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
- Smart Devices as Combination Products: Design and Regulatory Challenges
- Innovation and Future Directions of Drug Delivery Device Design and Development
- And More!

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GESSNET (Advanced medical product safety engineering) · SMC Ltd. · CereMentum · Suttons Creek, Inc. The Device Team for Pharma · reformulate health · CCL · gerresheimer · YPSOMED SELFCARE SOLUTIONS

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Tuesday, May 16, 2023

7:15 *Complimentary Breakfast & Registration*

8:10 *Chairperson Alie Jahangir's Welcome and Opening Remarks*

Regulatory Spotlight—Device Requirements for EU Clinical Studies

8:15 **Integral Device Requirements for EU Clinical Studies**

Catharine Strom, Director, Device Regulatory Lead, Sanofi

The French HA (ANSM) has recently requested device information for clinical studies (i.e., GSPR checklist/compliance statement, risk management data, biocompatibility assessment) which has not been required by other countries in the EU. With the implementation of EU CTR and the standardization of clinical study reviews, a hot topic is if the ANSM requirements will become the EU expectation. This presentation will explain the current regulatory framework which enables ANSM to require this data, strategies for complying with the ANSM requirements and assessment of the expectation under the EU CTR process. Key topics covered in this presentation include:

- The regulatory framework for medical products with integral devices for clinical studies in EU
- Managing diverse country-specific requirements for integral devices
- Developing integral devices compliant with EU CTR requirements

8:55 **Combination Product Usability Insights from Post-market Surveillance**

Amit Khanolkar, Sr. Director, Combination Product & Device PQM, Janssen Pharmaceuticals

Abstract Coming Soon

9:35 *Networking Coffee Break*

Technology Spotlight—On-body Delivery Devices

10:05 **On-Body Delivery Systems (OBDS): Functional, Quality and Usability Considerations**

Sriram Natarajan, Senior Engineer, Johnson & Johnson

Abstract Coming Soon

10:45 **Impact of On-body Delivery (OBD) Devices on Drug Development: Key Considerations and Risk Factors**

Kinsuk Shah, Director of Device Development, Viridian Therapeutics

As the prevalence of on body delivery devices continues to rise, drug development considerations need to be taken earlier to benefit from the flexibility of the large volume. Historically, drug development has been focused on maximizing concentration and reaching the 1ml or 2ml delivery space. However, with multiple launches on the SmartDose platform and future launches with other wearable platforms in progress, considerations may need to shift from high concentration to higher volume to maximize the capabilities of wearables, whether it is through longer shelf life, more comfortable patient considerations or improved delivery profiles. Lastly OBD devices introduce their own risk factors to be considered, whether it is through the adhesive pad and interaction with patients, disposal of electronic components or more complex human factors.

11:25 *Gessnet Pre-lunch Presentation*

Fubin Wu, Co-founder, Gessnet

11:45 *Complimentary Lunch, sponsored by*

GESSNET
Advance medical product safety engineering

Critical Issues— Digital Health Care & the Future of Combination Product Development

1:00 **Connected Drug Delivery Devices—Challenges Today and What the Future Holds**

Michael Song, Associate Director of Device Development, Takeda

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

1:40 **The Intervention + Prevention Combination Product: A Paradigm Shift in the Management of Chronic Inflammatory Conditions**

Dr Ramin Rafiei, PhD, Co-founder & CEO, Reformulate Health, & Dr Timothy Aungst, PharmD, Assoc. Professor, Massachusetts College of Pharmacy & Health Sciences

For many chronic autoimmune conditions, medical interventions are highly efficacious for long term management, but they often require a holistic approach that includes prevention as well as intervention. Biologics in specialty pharmacy products constitute half of total drug spend and have high chronic utilization. Despite their potential benefits, the current siloed approach to addressing a patient's health needs can limit the efficacy of these products. Market attempts to bridge this gap have often fallen short, failing to go beyond a connected injector or facilitating a bidirectional relationship between a patient and an app.

However, the introduction of Prevention-as-a-Service (PaaS) as a viable model offers a promising solution. PaaS can go beyond the current approach by addressing a patient's health needs in a more holistic way, through the integration of combination products and digital health management services. This approach may offer a more comprehensive solution for managing chronic conditions and improving patient outcomes. This talk will review the market's attempts at bridging this gap and explain why the best solutions have failed. It will also discuss the potential benefits of PaaS as a way to enhance the use of combination products in disease management, and how this approach may help to address the challenges associated with chronic conditions taking into account a greater continuum of human wants and needs, with a holistic and dynamic approach. By leveraging the benefits of combination products and digital health management services, PaaS may pave the way for more effective and comprehensive disease management strategies.

2:20 ***Afternoon Networking Break***

2:50 **How Digital Transformation and Predictive Engineering are Shaping the Future of Design**

Alie Jahangir, Senior Principal Quality Engineer, Combination Products, Janssen Pharmaceuticals

Abstract Coming Soon

3:30 **Beyond Combination Products**

Rodan Zadeh, Principal Consultant, Cerementum

Digital health products play a critical role in driving the adoption of widely used Telehealth and Decentralized Clinical Trials. Yet, under 21 CFR 3.2 definition, these products aren't classified as Combination Products. Although not in the same category, digital products' efficacy and delivered value are critical in today's health paradigm. In this session we discuss the various applications of digital technologies that are enhancing, enabling and elevating the true value of combination products. The topics discussed will include: overview of digital health products, health platforms, and how they address patient and clinician user requirements.

Roundtable Discussion

4:10 **Digital Healthcare—Current Opportunities & Future Trends**

Moderator: Alie Jahangir, Janssen Pharmaceuticals





Panelists:
Rodan Zadeh, CereMentum
Ramin Rafiei, Reformulate Health
Timothy Aungst, MCPHS
Michael Song, Takeda

Discussants:

The Audience

4:50 ***Happy Hour Mixer***

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

Wednesday, May 17, 2023

7:30 *Complimentary Breakfast, sponsored by*

gerresheimer

8:15 **Drug Delivery Device Development: Challenges and opportunities for Subcutaneous Self-Administration of Biopharmaceuticals**

Dr. Reza Abedian, Senior Medical Affairs Manager, Gerresheimer Medical Affairs & Applied Technologies, Gerresheimer

The pharmaceutical industry shows a growing trend towards a significant increase in the clinical development of biologicals, most specifically monoclonal antibodies (mAbs). Currently seven of the top ten selling drugs globally are biopharmaceuticals. The majority of mAbs have high viscosity and are often available in large volumes. This, together with high costs and resources required for intravenous administration for these medications, is pointing to subcutaneous self-administration as a suitable alternative.

The Center for Devices and Radiological Health (CDRH) recognizes that the voices and perspectives of patients are critical to understanding the impact of medical devices. Hence, it is crucial to implement a user-centric approach in the development of drug delivery devices. This presentation will outline the role of early-stage user insight studies, together with human factor evaluations, to ensure that voices of patients inform the development of drug delivery devices for subcutaneous injection of large molecule, highly viscous biologics. Moreover, there will be a review of the current device concepts addressing unmet needs of patients and healthcare professionals in order to further improve patient experience. Finally, the challenges associated with each drug delivery concept will be presented including, but not limited to, cold chain requirements and sustainability standards.

Critical Issues—Ensuring Quality and Safety in Combination Products

8:35 **Understanding Essential Performance Requirements (EPR's) and Testing for Combination Products**

Jennifer L. Riter, Senior Director, Business and 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.

9:15 **Essential Performance Requirements: From Design Controls to Control Strategies Throughout Drug Delivery Product Lifecycle**

Ling Lu, Associate Director, QE, Bristol Myers Squibb

This presentation highlights Essential Performance Requirements (EPRs) for ensuring the safety, efficacy, and quality of drug delivery products. It illustrates defining EPRs during the design controls and integrating them into Quality by Design (QbD) principles and control strategies, including incoming, in-process, release, and stability specifications for manufacturing. It also outlines the use of risk management and postmarket surveillance to ensure the long-term effectiveness of the control strategies. Overall, this presentation provides insights into managing EPRs in design controls, control strategies, and lifecycle management for drug delivery products, ultimately leading to the delivery of safe and effective products to the users and patients.

9:55 *Networking Coffee Break*

10:25 **Developing & Implementing an Integrated Risk Management Strategy Across the Combination Product Lifecycle**

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

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

- Combination-product 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.

11:05 **Achieve Business Success Through Effective Design Controls and Risk Management**

Fubin Wu, Co-founder, Gessnet

The goal of design controls and risk management is ultimately to ensure that medical products are safe and effective, which is also a fundamental measure for achieving business success. The best practices of design controls and risk management should be measured by how effectively they contribute to the success in launching and maintaining a safe and effective product.

Through examples, this presentation will illustrate how to effectively apply design controls and risk management for a drug delivery combination product. This includes 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.

11:45 **Adapting to How Patients Want to Consume Their Instruction for Use**

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

CCL Healthcare has enabled pharmaceutical manufacturers to enhance user experience, human factors, and drug delivery safety, while also improving compliance and patient outcomes through a wide range of patient instructions. The use of multi-color printed patient information has proven to be an effective way to educate patients and physicians on how to properly use or prepare medication, in a clear and concise manner. We will also discuss available options for digital IFUs as a supportive means of patient education, as well as possibilities for the future of secondary packaging.

12:05 ***Complimentary Lunch, sponsored by***

CCL

Spotlight on Device Development— Practical Considerations & Case Studies

1:15 **An Integrated Approach to Combination Product Development**

Asmita Khanolkar, Senior Director of Medical Device/Pharma Strategy & Commercialization, SMC Ltd.

With the growth of novel therapeutics and focus on combination products, "speed to clinic" is more critical than ever. Precision medicine therapeutics target a more specific indication resulting in a smaller potential market, the overall revenue projection along with available clinical study patients are reduced as seen in such markets. The formulations involved are more complex and pose many unknowns and uncertainties through-out the development. Along with optimizing delivery for the challenging needs of the formulation, the device design needs to incorporate patient requirements and deliver value. From the technical challenging needs of the formulations, to the patient interface side of things, an integrated "patient-centric" approach is necessary for device development. The presentation will discuss the trends and considerations towards development of drug delivery devices and path towards end-to-end solution from development to commercialization that can save time to clinic.

1:55 **Parallel Development: How Multiple Development Pathways for Combination Products Can Reduce Risk and Potentially Address More Unmet Medical Needs**

Jonathan Amaya-Hodges, Director of Technical Services, Suttons Creek, Inc.

The traditional approach to drug delivery combination product development has been single-track due to the high costs, high risks, and long timelines involved, however this often leads to significant delays or failures due to late-breaking negative data or regulatory setbacks. Additionally, there are a number of cases where commercialized combination products do not achieve commercial success for various reasons not considered during development, potentially ceding market share to rivals or failing to establish a viable market. As cutting costs/risks/timelines are typically not feasible, alternative mechanisms must be explored in order to increase probability of success. Parallel development is an intriguing approach, and one that does have some level of precedent in the industry. Although increasing initial development costs, parallel development reduces overall risks, may reduce (or at least keep constant) timelines, and, as an interesting byproduct, may address more unmet medical need and/or ultimately aid in achieving commercial success. Opportunities to expand usage of this approach will be explored, along with how to potentially implement with reasonable efficiency.

2:35 *Afternoon Coffee Break*

2:50 **Human Factors—A Crucial Element of Device Design**

Sara Waxberg McNew, Chief Scientific Officer, Design Science Group, Inc.

Abstract Coming Soon

3:30 **Large Volume Injections: At the Crossroads between Handheld Devices and Wearables**

Reto Falk, Director of Business Development, Ypsomed AG

This presentation will consider large volume injections in the context of current market trends and device options. Key takeaways include:

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

4:10 *Close of Program*

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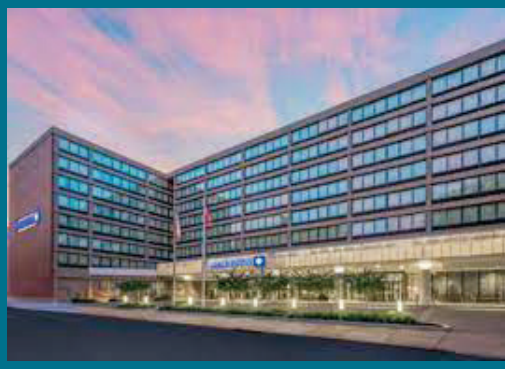
Located in Philadelphia (Center City), Wyndham Philadelphia Historic District is within a 10-minute walk of Liberty Bell Center and Independence Hall. This eco-friendly hotel is 0.9 mi (1.4 km) from Pennsylvania Convention Center and 1 mi (1.5 km) from Reading Terminal Market. Enjoy recreational amenities such as an outdoor pool and a 24-hour fitness center. Additional features at this hotel include complimentary wireless Internet access, concierge services, and gift shops/newsstands. Featured amenities include a business center, complimentary newspapers in the lobby, and dry cleaning/laundry services. Self-parking (subject to charges) is available onsite. Enjoy American cuisine at Coins Restaurant and Pub, a restaurant which features a bar/lounge, or stay in and take advantage of the room service (during limited hours).



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Dates:	May 16-17, 2023
Venue:	Wyndham Philadelphia Historic District
Venue Address:	400 Arch Street Philadelphia, PA 19106
Venue Phone:	215-923-8660

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