PharmaED RESOURCES, Inc.

Combination Products Summit 2022

Product Development, Quality, Safety, & Regulatory Compliance

September 28–29, 2022, Philadelphia PA

Featuring Lessons Learned & Case Studies from Industry Experts:

Jeff Givand
Exec. Director
Merck

Tina Tubbs
Assoc. Director
Sanofi

Susan Neadle
President
CP Consulting Services

Khaudeja Bano
VP CP Quality
Amgen

Amit Khanolkar
Sr. Director
Janssen Pharmaceuticals

Alie Jahangir
Sr. Principal Engineer
Janssen Pharmaceuticals

Ramin Rafiei
Co-founder & CEO
Reformulate Health

Sriram Natarajan
Janssen Pharmaceuticals

Jonathan Amaya-Hodges
Director, Technical Services
Suttons Creek

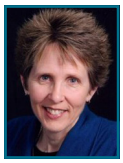
Jennifer Riter
Sr. Director
West

Parsa Famili
President & CEO
Novatek International

Timothy Aungst
Assoc. Professor
MCPHS University

Rodan Zadeh
Senior Director
Aetion

Asmita Khanolkar
Sr. Director
SMC Limited



Cheryl Stults
Principal
C&M Technical Consulting

Diane Harper
Senior Director
Immunovant, Inc.

And Comprehensive Coverage On:

- Meeting Regulatory Requirements in an Evolving Global Landscape
- Developing Combination Products for Challenging Unmet Needs
- 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
- Obtaining a Positive Notified Body Opinion for a Legacy Product—A Case Study
- 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)
- And More!

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Wednesday, September 28, 2022

7:45

Complimentary breakfast Chairperson Alie Jahangir's opening remarks

Spotlight on Design & Governance Across the Product Lifecycle

8:30

Best Practices for Cross-Functional Engagement Throughout the Combination Product Lifecycle

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

Development of drugs, biologics, and medical devices alone takes strong cross-functional engagement throughout development as well as in the postmarket setting, but these ties become even more critical for combination products. Combining multiple types of regulation while introducing innovation and complexity, such products require additional disciplinary support beyond that for the individual constituents, adding device development/engineering, device-specific regulatory and quality functions, along with risk management and human factors specialists to the existing drug or biologic team. Coming from different background and sometimes using different terminology, this poses a gap that must be filled to make the team truly cross-functional and, ultimately, successful at bringing a combination product to market and being a commercial success.

This presentation will share best practices for bridging the 'device vs. drug' gap at combination product manufacturers, considering other key functions (Clinical, Commercial, Program Management, Manufacturing, Supply Chain, etc.) as well as third party involvement (suppliers, CMOs, CROs, partners/collaborators, affiliates, etc.). It will build off of years of experience in developing, gaining approval for, and sustaining combination products, particularly drug- or biologic-delivery systems, and will consider common obstacles and how to overcome them. While challenges continue to affect the combination product industry (EU MDR, US postmarket safety reporting rule, ICH Q12, new guidance, etc.), developing and supporting such products can adapt and become more efficient in order to address patients' needs expeditiously.

9:15

Developing Combination Products for Challenging Unmet Needs

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

Pharmaceutical trends today are shifting towards targeted therapies, precision and personalized medicine for patients from hospital settings to home. The evolving novel therapies in bio therapeutics and long acting injectables pose new challenges for combination products in drug delivery. In addition to the complexity of the therapy, the formulations can be challenging to deliver due to viscosity or high doses, pose unknown pathways and delivery sites and highlight the limitations of current device technology and long development cycles. This presentation will look at some of these challenges and the direction towards patient-centric development of drug delivery devices, especially for autoinjectors. Putting the user case at the heart of the process, the device design must additionally satisfy functional, cognitive, aesthetic and emotional balance. This requires flexibility in device design space for both the inside and outside and means to support adaptive and flexible sterile manufacturing. This leads the discussion towards an integrated approach for drug-device development and a path from development, small batch manufacturing to commercialization that can save time to clinic.

10:00

Networking Coffee Break

10:30

Combination Product Early Development: Technical, Quality & Clinical Considerations

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

Breakthrough innovations in drug and biologic based therapies as well as technological developments in design and development of medical devices have led to the rapid rise in the use of drug-device combination products in the last few decades. The desire to bring innovative therapies to patients through combination products and the resulting market and regulatory pressures presents unique challenges to development teams, especially with the need to balance risk with the speed of development. Agile and efficient development strategies involve leveraging risk-based approaches rooted in the application of scientific and engineering principles to the design, process and use of the combination product. This presentation highlights industry best practices in early development including development strategy considerations, first-in-human readiness and the safety assurance of the combination product.

Technology Spotlight—On-body Delivery Systems

11:15

Development of On-Body Deliver Systems (OBDS)

Sriram Natarajan, PhD, Janssen Pharmaceuticals

OBDS represent a growing drug delivery platform that encompass a range of technologies, delivery volumes etc. While there are some common aspects to established delivery devices such as auto-injectors, there are also differences. Relevant standards and guidances for OBDS are still at early stages so companies and regulatory agencies interact and align on various aspects related to design and development, often when product development is ongoing. There will be an overview of different technologies, relevant standards and quality considerations in this presentation.

12:00 *Complimentary Networking Lunch*

1:15 **PQRI Combination Products Working Group Update—Meeting Challenges with Material Qualification for Combination Products**

Cheryl LM Stults, PhD, Principal, C & M Technical Consulting, LLC, and Diane Harper, PhD, Senior Director, Regulatory-CMC, Immunovant, Inc.

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.

2:00 **Obtaining a Positive Notified Body Opinion for a Legacy Product—A Case Study**

Tina Tubbs, Associate Director, Global Regulatory Affairs – Devices, Sanofi

A notified body opinion is a requirement for single integral products, such as a PFS, under MDR Article 117. This case study describes how a positive notified body opinion was achieved for a legacy product that was developed prior to design control regulation (2017) and was submitted as a market expansion.

2:45 *Networking Coffee Break*

3:15 **Global Combination Products Landscape and Harmonization Opportunities**

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

The prevalence of combined use products continues to grow in the marketplace to support administration of medicines or to enhance the action of medical devices. Regulators globally recognize the higher technical complexity of these products warrants strengthening their associated authorization and certification requirements to ensure product safety, efficacy and usability. With that, the regulatory landscape for combined use products is increasingly complex. There are a variety of terminologies and interpretations applied across jurisdictions globally with respect to "Combination Products" and related terms associated with medical products intended for combined use. Some jurisdictions do not even call these "combination products." Regardless of nomenclature, there are common issues and considerations to be addressed for combined use medical products. In particular these include systems (the constituent parts and the combined use medical product as a whole) risk-based approaches to development and lifecycle management, ensuring safe and efficacious combined use of constituent parts, robust collaboration and coordination with suppliers, and sustained market supply for the intended use(s), user(s) and use environment(s). Classification and regulatory constructs for combined use medical products across jurisdictions are neither stable nor consistent across global jurisdictions. As technology continues to rapidly evolve, harmonization opportunities are evident. Industry needs to exercise caution and be aware of what regulations apply to such combined use products across jurisdictions. This presentation will:

- Review the dynamic combination product global regulatory landscape
- Review harmonization efforts underway, including:
- ASTM International Combination Product Standard Definitions.
- FDA Proposed rule on 21 CFR 820 harmonization with ISO 13485:2016
- WHO
- ISO 14971:2019 and AAMI TIR 105:2020
- ISPE Module 2 risk-based QoS Harmonization effort

Closing Panel Discussion

4:00 **The Changing Regulatory Landscape for Combination Products—A Roundtable Discussion**

Moderator: Alie Jahangir, Janssen Pharmaceuticals





Panelists:

- Jonathan Amaya-Hodges, Suttons Creek
- Amit Khanolkar, Janssen Pharmaceuticals
- Susan Neadle, Combination Products Consulting
- Tina Tubbs, Sanofi

Discussants:

The Audience

4:45 *Happy Hour Mixer*

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

Thursday, September 29, 2022

7:45 *Complimentary Breakfast*

Technology Spotlight—Digital Health Care & the Future of Combination Product Development

8:30 **Beyond Combination Products**

Rodan Zadeh, Senior Director, Go-To-Market Strategy, Aetion

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.

9:15 **Digital Transformation and Predictive Engineering are Shaping the Future of Design**

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

Emergence of digital technologies in various industries have been occurring at an astounding pace over the past decade. Healthcare is one of the key industries that can significantly benefit from this technological revolution. Application tools such as computational modeling and simulation (CM&S) as well as Data Analytics, could optimize drug and medical device development and regulatory research, with the capability to accelerate access to safe and effective products. Furthermore, manufacturing technologies continue to evolve as the internet of things, artificial intelligence, robotics, and advanced computing begin to challenge the traditional approaches, practices, and business models for the manufacture of pharmaceuticals and medical devices. The application of these technologies has the potential to dramatically increase the agility, efficiency, flexibility, and quality of the industrial production of both medicines and medical devices. How these technologies are deployed on the journey from data collection to the hallmark digital maturity of Industry 4.0 will define the next generation of pharmaceutical and medical device manufacturing. Achieving the benefits of this future requires a vision for it and an understanding of the extant regulatory, technical, and logistical barriers to realizing it.

10:00 *Morning Coffee & Networking Break*

10:30 **Home as the Centre of Care: Integration of Next Generation Drug Device Combination Products With Decentralized Care Pathways and Future Clinical Research**

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

The COVID-19 pandemic has reshaped our world and our approach towards clinical research and patient care. The result has been a complete inversion on the risk-benefit ratio for many innovative technologies and their associated business models, which have evolved patient-centric clinical research and care pathways towards decentralization. The near ubiquitous nature of drug-device combination products, growing utilization of telehealth and disease management apps, and prevalence of remote patient monitoring tools all evidence this shift. This talk will focus on the real work that needs to be done as a collaboration to successfully integrate new generation drug product delivery devices with a decentralized healthcare patient journey. Specifically, we will address the following five critical pillars: 1) delivering medicines to patients without damage or compromise 2) ensuring effective use of the medications at home 3) remotely managing and monitoring the health condition 4) handling newly generated data streams 5) implications for payors and health systems. Our framework will also include models within select chronic conditions namely diabetes, atopic dermatitis and rheumatoid arthritis.

Roundtable Discussion

11:15 **Digital Healthcare—Current Opportunities & Future Trends**

Moderator: Alie Jahangir, Janssen Pharmaceuticals

Panelists:

- Rodan Zadeh, Aetion
- Ramin Rafiei, Reformulate Health
- Timothy Aungst, MCPHS

Discussants:

The Audience

12:00 *Complimentary Lunch*

Critical Issues—Ensuring Quality and Safety in Combination Products

1:15 **A Control Strategy Framework for the Quality Attributes of a Parenteral Combination Product**

Jeff Givand, Executive Director, Device Development R&D, Merck

This talk will highlight a case study in the design, development and manufacturing control strategy establishment of an injection device to assure the quality attribute, injection force, was robustly achieved. A detailed understanding of the device design and all design factors that contributed to the injection force experienced by the user was developed leading to creation of a holistic set of manufacturing process controls capable of ensuring the injection force design requirement was robustly achieved.

2:00 **Establishing a Contamination Control Strategy Via Automation**

Parsa Famili, President & CEO, Novatek International

The success, safety and effectiveness of any biologic-device combination product, hinges upon a robust and practical contamination control strategies. To assist pharma and medical device manufacturers, the new EU GMP Annex 1 provide Contamination Control Strategy with focus on Viable/Microbial Air Monitoring. Essentially, the Total Contamination Control Strategy (TCCS) starts with proper determination of Maximum Safe Carryover, calculated based on health-based exposure limits, a routine cleaning program to evaluate effectiveness of the steps used, followed by microbial Environmental Monitoring, Water and Utilities Monitoring, HVAC filter qualifications, Media Fills, and personnel monitoring, which completes the contamination control cycle and delve into the application and necessity of these processes for combination product manufacturing. This presentation aims at providing a comprehensive review of EU GMP Annex 1 and practical instruction in ensuring sterility in both biologic and device constituent of the combination products.

2:45 ***Afternoon Break***

Critical Issues—EPRs, A Risk-based Approach

3:00 **Essential Performance Requirements for Combination Products**

Jennifer Riter, Senior Director, Business & Technical Operations, West Pharmaceutical Services, Inc., & 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 application. This entails addressing risk-based scientific and technological considerations raised by combined use of the differently regulated medical products and the combination product system as a whole. Understanding on how to identify Essential Performance Requirements (EPRs) as well as determining the analytical approach and control strategies for EPRs is critical to the development of a combination product.

The presentation will:

- Review the FDA regulatory guidance for EPR's to be published in June/July 2022
- Review a risk-based approach to identify EPRs
- Provide examples of common EPRs
- Build understanding of EPR characterization and analytical considerations

Spotlight on Postmarket Safety Reporting

3:45 **Current State of Postmarket safety reporting for combination products – post implementation**

Khaudeja Bano, VP of Combination Product Quality, Amgen

This presentation will cover the following key issues facing postmarket safety reporting protocols, including:

- Industry best practices to meet evolving regulations through effective compliance strategies
- Building an organizational structure to support postmarket safety reporting for combination products
- Examples of effective approaches to maintain reporting for combination products
- Evolution of global regulatory landscape for combination product reporting and advice to be best prepared

4:30 ***Close of Program***

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About your conference destination:

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Register for the conference using one of three options:
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Venue:	Wyndham Philadelphia Historic District
Venue Address:	400 Arch Street Philadelphia, PA 19106
Venue Phone:	215-923-8660

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Standard Registration	$1,695
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