Combination Products Virtual Summit 2020
July 28–29, 2020, Online EDT

Featuring Lessons Learned and Case Studies from Industry Experts:

And Comprehensive Coverage On:

- Determining Appropriate Regulatory Pathways for Post-market Changes, Essential Performance Requirements (Erps), Control Strategies, Life Cycle Management and Platforming
- Post-approval device changes and New EU MDR 117 Requirements: Implication for Combination Products
- Preparing for the Digitalization Trend in Combination Product Use and Design
- Integrated Approach and Strategy in Developing Drug/Biologic/Device Combination Products
- Wearable Devices and the Changing Paradigm in Drug Delivery and Combination Product Development
- Leveraging the Capabilities of Human Factor Engineering in Digital, Connected Health and Drug/Biologic Applications
- Application and Characterization of Biodegradable Polymers as a Drug Delivery Conduit in Combination Products
- Application of Mathematical Modelling in Design and Validation of Drug/Biologic/Device Combination Products
- Combination Product Development: Real World Challenges for a Pharmaceutical Organization
- A System-Wide Approach to Stability of Combination Products
- Translation of User Research to Actionable Product Specification
- Control Strategy and Design Transfer for Pharmaceutical Delivery Device Combination Products
- Integrated Development and Risk Management Process for Combination Products
- Post-market Safety Reporting: An End to End Approach

With Representation From:
Pharma Ed’s Combination Product Virtual Summit 2020
Sponsored by:
Combination Products Virtual Summit 2020

Tuesday, July 28, 2020,
Eastern Daylight Time

8:30
Chairperson’s Welcome and Opening Remarks
Alie Jahangir, Ph.D., Senior Principal Engineer, Combination Product & Emerging Technologies, Janssen Pharmaceuticals

8:40
Combination Product Topics of Interest:
EPRs, Control Strategies, Lifecycle Management and Platforming
Carolyn Dorgan, Senior Team Lead, FDA

9:20
The Utilization of Regulatory Intelligence in the Evolving Landscape for
Combination Products, Medical Devices and Digital Health Solutions
Darin Oppenheimer, Ph. D., Executive Director, Regulatory Devices & Digital Health Solutions, Merck

10:00
Morning Break & Sponsor Presentations

10:20
Combination Product Development—Real World Challenges for a Pharmaceutical Organization
Amit Khanolkar, Senior Director, Combination Products & Emerging Technologies, Janssen Pharmaceuticals

When a Pharmaceutical Organization develops and commercializes a drug-device Combination Product, it faces several challenges which stem primarily from cultural differences in the Pharmaceutical and Medical Device worlds. One such real world challenge is in the Design Transfer of the Combination Product. Design Transfer is the process of transferring the product design (Design Specifications) to commercial manufacturing (Manufacturing Specifications) resulting in product that meets the original design intent and specifications. While Design Transfer in the Medical Device world is in principle equivalent to Technology Transfer in the Pharmaceutical world, several practical challenges are encountered and have to be overcome to successfully transfer the design to commercial manufacturing.

This presentation will highlight Design Transfer challenges and mitigation strategies from several years of experience successfully transferring multiple combination product by a Pharmaceutical Organization.

11:00
Constructing a Robust and Reliable End-to-End Stability Program for Combination Products.
Alie Jahangir, Ph.D., Senior Principal Engineer, Combination Product & Emerging Technologies, Janssen Pharmaceuticals

Combination products are unique therapeutics that combine two or more regulated constituent parts (i.e. drugs, biological and/or devices), leading to products that provide ease of use, safer and more effective. While the combination products have been developed and commercialized as a result of unprecedented collaboration between pharma and device industries to address patients’ unmet therapeutic needs, they also have presented new regulatory, quality and development challenges. One such key challenge is the absence of a harmonized development/guidance/framework for combination products. In the absence of such a coherent paradigm, the manufacturers face significant risks in properly implementing consistent and effective strategies that ensure product safety, efficacy and functionality. Specifically, there are currently no established stability testing guidances that apply to combination products. This presentation, therefore, proposes unique set of practical and proven strategies that would assist the manufacturers of combination products to design, plan and execute a flawless stability testing program throughout its entire supply chain. This new stability paradigm represents an integrated and system-based approach that ultimately ensures the safe delivery of our product to our patients, while meeting all the regulatory, quality and compliance requirements.
Jonathan Amaya-Hodges, Associate Director of Regulatory Affairs, Biogen

One of the most significant global topics in medical device today is the implementation of the Medical Device Regulation (MDR) in the European Union, given the imminent effective date in May 2020. An associated concern that has yielded discussions and even more questions is the impact of MDR Article 117 on combination products in Europe. The text of the MDR provides limited information, but this area is in a constant state of flux with a Q&A document issued by the European Medicines Agency (EMA) in February 2019 followed by a draft guidance in June. Meanwhile, industry has provided input via multiple reflection papers dating back to 2018, and has continued input including numerous comments to said draft guidance. With the implementation date quickly approaching, we expect further changes and clarifications in the near future.

Items to discuss include the regulatory status of combination products—from “single-integral” devices to medicines co-packaged with devices to so-called “cross-labeled” products, the Notified Body Opinion (NBOp) prescribed per Art. 117, the designation of Notified Bodies (or lack thereof), the definition of a change to an existing product requiring a NBOp, timing considerations, and more. While we do not have all the answers, forums like this afford us the opportunity to share available pieces of information and clarify expectations for innovative products to address unmet medical needs.

Roundtable Discussion

The Changing Regulatory Landscape for Combination Products—What You Need To Know

Moderator: Alireza Jahangir, Janssen Pharmaceuticals

Panelists:
- Carolyn Dorgan, FDA
- Darin Oppenheimer, Merck
- Jonathan Amaya-Hodges, Biogen
- Amit Khanolkar, Janssen Pharmaceuticals

Discussants:
- The Audience

Integrated Strategy and Approach to Combination Product Development for Biologics

Rajiv Gupta, Ph.D., Director, Takeda

Combination products such as pre-filled syringes and autoinjectors continue to be developed and commercialized for biologics. Such product presentations provide patient-centric delivery options to patients in a home environment for self-administration and health care professionals in an office environment. The development of these drug-device combination products from concept to commercial requires input from several functions working in a collaborative manner.

This presentation discusses an integrated strategy and considerations around device platform approaches and how to potentially bridge between devices. It also discusses the high-level process and feasibility/development activities that are typically conducted in a cross-functional team structure to enable the start of clinical trials and regulatory submissions.

Afternoon Break & Sponsor Presentations

Translation of User Research to Actionable Product Specification

Lindsay Carrabine, Design Director, Design Science Consulting

In today’s market of combination products, drug efficacy isn’t the only market differentiator anymore. Usability of the delivery system has become a driving force in purchasing decisions for healthcare providers and their patients. A vital step to establishing features that will reduce the potential for errors while increasing efficiency, intuitiveness, memorability, and satisfaction is understanding your users, use environments and their use of the product. There are many methods for conducting user research that result in a multitude of data. However, it is the analysis of the data collected during these methods and the format in which the data is translated and visualized that is the key to making the effort valuable.

Technology Spotlight—Biodegradable Polymers & Ocular Device Delivery Systems

Biodegradable Polymers in Drug Delivery

Gregory Grover, Chief Technical Officer, Contraline, Inc.

Biodegradable polymers are frequently investigated for controlled delivery of therapeutics in vivo. Potential benefits of these systems over oral dosing includes improved patient compliance, reduction in side effects, and decreased therapeutic payload. Generally, biodegradable polymer formulations contain degradable moieties like esters/anhydrides and amides that are prone to hydrolysis and enzymatic cleavage; respectively. The modes of degradations for these systems are generally described as either surface or bulk degradation. In this talk a brief overview of FDA approved products using biodegradable systems will be presented. Bulk versus surface degradation approaches and subsequent release profiles will be discussed. Aspects of how choices in polymer composition, formulation processes, and properties of the therapeutic(s) can impact the final product’s properties will be highlighted.

End of Day One.
Wednesday, July 29, 2020, Eastern Daylight Time

8:30
Pharma Ed Welcome and Chairperson’s Opening Remarks

8:35
The Safety Imperative: A Growing Market for Safety Syringes in the Home and the Hospital
Richard Harrison, Manager of Strategic New Platforms, Owen Mumford

Since the passage of sharps safety legislation in the USA and Europe, use of safety-engineered drug delivery devices has become mainstream. However, in addition to regulatory requirements for healthcare settings, there are also other factors driving the growing use of safety devices. Firstly, administration of medication by injection in the home or in non-hospital settings is increasingly prevalent, partly due to longer life expectancies and the resulting pressure on healthcare systems. Secondly, younger populations are experiencing a rise in chronic diseases, which require more frequent subcutaneous injection. Thirdly, a vast number of original reference biologics are reaching expiry for patent exclusivity, and these are typically administered via subcutaneous injection. As a result of these combined factors, safety-engineered pre-filled syringes are expected to dominate the market in coming years, occupying approximately 76% of the share of total pre-filled demand in 2023. With demand growing across the globe, market-leading pre-filled safety-engineered devices must respond to the various needs of user segments, integrate safety mechanisms, provide robust sharps protection, accuracy of drug delivery and ease of use.

9:00
Critical Issues—Building a Robust Stability Testing Program

Wearable Devices and the Changing Paradigm in Drug Delivery and Combination Product Development
Carl Dabruzzi, Director, Product Management, Self-Injection Systems, West Pharmaceutical Services

Over the past decade, the growth of biologic drug formulations has been driving a significant shift in thinking about how injectable drug products can be administered to patients. These higher volume, higher viscosity products would have historically required administration by a healthcare professional in a hospital or clinical setting. However, this is no longer the case. The medical device industry has stepped up to meet the delivery challenges of these new therapies and, in the process, opened the door to a whole new set of opportunities involving legacy IV-administered products. This presentation will provide a review of the general landscape of the technologies being developed to serve these customer needs along with some of the inherent benefits of the various technologies. The presentation will also include a list of important topics that should be discussed prior to selecting a partner and technology for your combination product development.

9:45
Combination Products Risk Management
Susan Neadle, Senior Director, Value Chain Quality Design, Johnson & Johnson

Combination Products regulations are evolving globally. One consistent undercurrent to this dynamic regulatory environment is the drive for successful practices and control strategies throughout the combination product lifecycle, to assure public health, ensuring risk is commensurate with product complexity and patient needs. In this presentation we’ll review combination products risk management considerations and essential performance requirements to support robust product development and lifecycle management.

10:25
Morning Break & Sponsor Presentations

10:45
Post-market Safety Reporting: An End to End Approach
Khaudeja Bano, Head of Medical Affairs & Medical Device Safety, Abbott Laboratories

Combination products by definition are therapeutic and diagnostic products that combine drugs, devices, and/or biological constituent parts to achieve the intended use. While innovative solutions have leveraged a combination of these constituents, providing a multitude of options for patients, they pose postmarketing safety, regulatory and implementation challenges for both the Food and Drug Administration (FDA) and the medical device and pharmaceutical/industry.

The Final Guidance for Industry and FDA staff issued in July 2019 “Postmarketing Safety Reporting for Combination Products” clarified safety reporting requirements for combination products in accordance with the final rule for Postmarketing Safety Reporting (PMSR) requirements for combination products that FDA issued on December 20, 2016 (81 FR 92603) and that is codified in 21 CFR Part 4, Subpart B.

Each constituent part of a combination product is governed by one of three differing sets of postmarketing safety reporting regulations, and while each set of regulations has similar provisions, there are significant differences among these regulations which address the unique characteristics of the product type. The PMSR requires combination product applicants to comply with the reporting requirements applicable to the type of marketing application used to approve or clear their combination product. Additionally, combination product applicants must comply with a subset of six specified reports based on the other constituent parts (drug, device or biological product).
Ideally, the industry needs to align on certain best practices related to PMSR. Discussing lessons learned and challenges with Implementation of PMSR in a global setting to develop solutions is the key objective of this session.

- Highlight the challenges and solutions faced by the industry in a global environment
- Best practices to streamline compliance for successful implementation by July 2020

A risk-based approach to PMSR decision-making — roles and responsibilities

### Critical Issues—Governance: Managing Risk & Performance Requirements Across Combination Product Lifecycles

#### 11:25 Integrated Strategy for Drug-Delivery Device Lifecycle Planning

**Diane Paskiet, Director, Scientific Affairs, West Pharmaceutical Services**

Integration of drug product requirements with delivery system safety and performance is a fundamental aspect of patient-focused drug development. It takes a concerted effort to safeguard user needs for the delivery device during preclinical phases when the drug product formulation and dosing is not yet defined. Although this is problematic, there are steps that can be taken in early drug development to identify and mitigate risks of the materials, and components to be built into the final system. This presentation will highlight aspects for planning integration of drug-delivery device from development to commercialization.

**Lunch Hour. Visit the Networking Chatroom**

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#### 12:05 Roundtable Discussion

**Implementing Risk Management, Performance Requirements & Safety Across Product Lifecycles**

**Moderator:** Alireza Jahangir, Janssen Pharmaceuticals

**Panelists:**
- Susan Neadle, Johnson & Johnson
- Khaudeja Bano, Abbott Laboratories
- Diane Paskiet, West Pharmaceutical Services

**Discussants:**
- The Audience

### 1:10 Implementing Risk Management, Performance Requirements & Safety Across Product Lifecycles

**Moderator:** Alireza Jahangir, Janssen Pharmaceuticals

**Panelists:**
- Susan Neadle, Johnson & Johnson
- Khaudeja Bano, Abbott Laboratories
- Diane Paskiet, West Pharmaceutical Services

**Discussants:**
- The Audience

### 1:50 Self-Administration to Self-Management—How Real-World Data Transforms Medications into Disease Self-Management Solutions

**Dr. Ramin Rafiei, Director of Digital Healthcare, SHL Group**

Poor adherence to safe and efficacious medications renders them unsafe and ineffective, resulting in considerable morbidity, mortality, and avoidable healthcare costs. Typically, 50% of patients with chronic conditions fail to take their recommended therapeutic dose consistently. Poor adherence also exacerbates the gap between clinical efficacy of medications, as determined in a randomized controlled trial setting, and their real-world effectiveness.

As a result, pharmaceutical and medical device companies should no longer rely on the effectiveness of combination products for chronic disease self-management; rather, they need to invest in new ways to help patients self-manage existing conditions. Augmentation of drugs through sensors and connectivity provides a digital representation of the patient’s true self-care behaviors and health outcomes. However, if improvements in adherence are to be realized, real-world data from connected devices need to be applied effectively towards improving the patient experience, and increasing engagement with their care plan.

This presentation demonstrates how connected therapeutics combine connected drug delivery devices with software and services to transform standalone medications into disease self-management solutions. This wager that connected therapeutics will add value to all stakeholders across the care continuum makes sense. For pharmaceutical companies, this benefit may best manifest itself in an ability to measure and improve the real-world effectiveness of pharmacotherapies.

### Critical Issues—Analytical Testing Methods for CPs

#### 2:30 Analytical Methods for Single Entity Combination Products

**Kurt Moyer, Ph.D., President, Pine Lake Laboratories**

The demand for sophisticated drug delivery has led to the development of many innovative combinations of pharmaceuticals, biologics and medical devices across a broad range of therapeutic areas. While single entity combination products have the potential to fulfill major unmet medical needs, they also present unique challenges in development and approval. One of these challenges is the development and validation of analytical methods to assess the quality, safety and stability of
the single entity combination product. To meet this goal, analytical methods are needed to evaluate the potency and stability of the device. In addition to these analytical methods, additional methods may also be needed to determine release/elution of the drug or biologic, evaluate uniformity of coatings, and monitor for leachables from the device. Depending upon the conditions of assembly of the single entity medical device, the analytical meth-
ods will need to be able to detect process impurities and unique degradants formed during the manufacturing process. In this presentation analytical testing strategies will be discussed to address the unique challenges presented by single entity combination devices.

Close of Program
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 2020** 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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