Combination Products Summit 2020
March 10–11, 2020, Philadelphia, PA

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:
Tuesday, March 10, 2020

8:00
Complimentary Breakfast & Chairperson’s Welcome and Opening Remarks

8:45
Combination Product Topics of Interest:
EPRs, Control Strategies, Lifecycle Management and Platforming

Carolyn Dorgan, Senior Team Lead, FDA

Combination Products are no longer niche products in the world and it is time to engage in a collaborative dialogue to explore best practices in combination product development including essential device performance requirements, lifecycle management and considerations for when design of platform devices are appropriate. Combination Product development requires a unique strategy beyond the established drug and device siloed development processes. By breaking down these traditional barriers, industry can create opportunities to leverage these concepts across multiple product lines and streamline development.

9:30
EU MDR Article 117 Impact on Combination Products

Jonathan Amaya-Hodges, Associate Director of Regulatory Affairs, Biogen

One of the most significant global topics in medical devices 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.

10:00
Exhibit Viewing & Networking Coffee Break

10:25
Post-Approval Device Changes and New EU MDR 117 Requirements: Implication for Combination Products

Leonel Vanegas, Director Devices & Combination Products, formerly Merck

As the new EU MDR 117/745 approaches combination products manufacturers will need to comply to certain annexes for notified bodies to grant CE marks for commercial distribution in EU. US Device regulatory requirements are new in US pharmaceutical companies, let alone legacy EU medical device directive which will become a regulatory requirements on May 28th, 2020.

Roundtable Discussion

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

Panelists:
• Carolyn Dorgan, FDA
• Jonathan Amaya-Hodges, Biogen
• Leonel Vanegas, Merck
• Alireza Jahangir, Janssen Pharmaceuticals

Discussants:
The Audience

11:25
Constructing a Robust and Reliable End-to-End Stability Testing Program

Alireza 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 developmental 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 guidelines 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.

Complimentary Networking Lunch

1:15 Wearable Devices and the Changing Paradigm in Drug Delivery and Combination Product Development

Carl Dabruzzi, Portfolio Manager, Product Development, 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.

2:00 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 healthcare 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.

2:40 Exhibit Viewing & Networking Coffee Break

3:05 Translation of User Research to Actionable Product Specification

Sara Waxberg McNew, Chief Research Officer, 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

3:45 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.

4:25 Risk Based Development for Usability of Ocular Devices

Mayumi Bowen, Senior Engineer, Genentech

An intravitreal injection enables highly targeted drug therapy, administering a small volume of medication directly into the space in the back of the eye. It is usually performed by a trained retinal specialist and an assistant in an office setting using sterile techniques. Considering the complex preparation steps required for an intravitreal injection and the critical patient safety considerations, designing an ocular injectable device has significant challenges. This presentation will address health authority guidance & requirements pertaining to patient safety associated with intravitreal injections.
Combination Products Summit 2020

Wednesday, March 11, 2020

8:45
Combination Product Development—Real World Challenges for a Pharmaceutical Organization

Amit Khanolkar, 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.

9:25
Integrating Control Strategy in Pharmaceutical & Device Development & Manufacturing for Combination Product Delivery Devices

Ling Lu, Design Control Group Lead, Senior Principal Scientist, Pfizer

This presentation explores how to integrate Quality by design (QbD) in Design Controls and control strategy in design transfer for combination products (CP). The prefilled syringe case is used to illustrate this approach.

- Control Strategy (CS) is a pharmaceutical terminology in QbD;
- PFS with drug as primary mode of action often developed and manufactured under pharmaceutical quality system, while the development of delivery devices followed design controls per device regulation;
- It is necessary to establish CS for PFS including device constituent parts to integrate controls satisfying both drug and device regulations;
- Develop CS for delivery device during design transfer, identifying critical quality attributes (CQAs) for device and transferring knowledge from design controls and manufacturing process development, generating a set of controls, e.g. incoming, in-process, release and/or stability specifications for delivery device manufacturing;
- Promote communication between device and drug development groups, development and manufacturing groups, pharma companies and syringe component suppliers, focusing on CQA and CS for the device constitutes and interfaces between drug and device;

Recognize the difference on the focus of CS between delivery device and drug, e.g. Drug focused more on critical process parameter (CPP) and Device focused more on critical material attributes (CMA).

11:10
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

Complimentary Networking Lunch

1:00 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.

Roundtable Discussion

1:40 Implementing Risk Management, Performance Requirements & Safety Across Product Lifecycles

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

Discussants:
- The Audience

2:10 Exhibit Viewing & Networking Coffee Break

2:35 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

3:20 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 methods 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.

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