Drug and Device Combination Products 2015: Navigating Regulation, Enhancing Collaboration, and Accelerating Development

September 28 – 29

Hyatt Regency Bethesda | Bethesda, MD

As of September 21, 2015

PROGRAM CO-CHAIRS

John (Barr) Weiner, JD
Associate Director for Policy and Product Classification Officer
Office of Combination Products, FDA

Winifred Wu, MBA, FRAPS
President and Principal Advisor
Strategic Regulatory Partners, LLC

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DIA is the only global organization dedicated to bringing health care product development professionals together in a neutral environment to improve health and well-being throughout the world.

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OVERVIEW:

Advances in scientific knowledge and technology are driving growth and innovation for combination products - therapeutic and diagnostic medical products that combine drugs, devices, and/or biological products with one another. This innovation continues to blur the historical lines separating traditional drugs, biologics, and medical devices. The regulatory landscape is dynamic and the development and marketing authorization pathways for combination products raise unique challenges when compared to drugs, devices, or biological products alone. These differences impact many aspects of product life cycle management, including preclinical and clinical evaluation, regulatory approval processes, manufacturing and quality controls, postmarket surveillance, adverse event reporting, promotion and advertising, and post-approval modifications.

This conference offers practical approaches for combination product development processes and regulatory requirements.

HIGHLIGHTS:

- Updates from FDA and other regulators
- Combination product cGMP requirements and practical approaches
- Current hot topics in marketing applications
- Collaboration with various partners in developing combination products
- Interactive case studies to enhance learning
- And more

LEARNING OBJECTIVES:

At the conclusion of this conference, participants should be able to:

- Describe the US regulatory framework for drug/device combination products
- Identify Current Good Manufacturing Practice requirements for combination products
- Discuss effective collaboration approaches with various partners throughout the product life cycle of combination products
- Recognize current issues facing combination product manufacturers and describe potential approaches to address these challenges
- Describe the current status of combination products including the emerging issues in the EU

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Type of Activity: Knowledge

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MONDAY, SEPTEMBER 28

7:30AM-5:15PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30-9:00AM WELCOME AND OPENING REMARKS

Susan Cantrell, RPh
Senior Vice President and Managing Director
DIA

Jill Hartzler Warner, JD
Associate Commissioner for Special Medical Programs
Office of the Commissioner
FDA

9:00-10:30 AM SESSION 1: FDA UPDATE ON COMBINATION PRODUCTS

SESSION CHAIR:

Steven Binion, PhD, MBA
Director
Policy, Technology and Communication
Corporate Regulatory Affairs
Becton Dickson

Leadership from the Office of Combination Products will provide an update on recent and pending activities at FDA. The discussion will address premarket and postmarket regulatory issues as well as agency systems and procedures to support a cross-cutting, collaborative approach to regulation of combination products.

SPEAKERS:

Thinh Nguyen, PhD
Director
Office of Combination Products, FDA

John (Barr) Weiner, JD
Associate Director for Policy and Product Classification Officer
Office of Combination Products, FDA

10:30-11:00AM **REFRESHMENT AND NETWORKING BREAK**

11:00AM-12:30PM SESSION 2: CGMP GUIDANCE – PART ONE

SESSION CHAIR:

Steven Binion, PhD, MBA
Director
Policy, Technology and Communication
Corporate Regulatory Affairs
Becton Dickson

In 2013, the Food and Drug Administration (FDA) published the final rule on the Current Good Manufacturing Practice (CGMP) requirements applicable to combination products. The rule is intended to clarify which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products. In addition, the rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products.

In Part One of this session, updates will be provided on the recently published draft CGMP guidance associated with the final rule and the ongoing dialogue between industry and FDA regarding implementation of the rule. In Part Two of this session, a panel of FDA representatives from CBER, CDER, CDRH, ORA, and OCP – all experts in combination product regulation – will share their learnings and answer questions from the audience on this important topic.

CGMP Guidance

John (Barr) Weiner, JD
Associate Director for Policy and Product Classification Officer
Office of Combination Products, FDA

12:30-1:45PM **LUNCHEON AND NETWORKING**

1:45-3:15PM SESSION 3: CGMP GUIDANCE – PART TWO – A PANEL DISCUSSION

SESSION CHAIR:

Steven Binion, PhD, MBA
Director
Policy, Technology and Communication
Corporate Regulatory Affairs
Becton Dickson

In 2013, the Food and Drug Administration (FDA) published the final rule on the current good manufacturing practice (CGMP) requirements applicable to combination products. The rule is intended to clarify which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products. In addition, the rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products.

In Part Two of Session Three, a panel of FDA representatives from CBER, CDER, CDRH, ORA, and OCP – all experts in combination product regulation – will share their learnings and answer questions from the audience on this important topic.

PANELISTS:

Steven Hertz, MBA
Consumer Safety Officer
CDER, FDA

Paula Katz
Director, Manufacturing Quality Guidance and Policy
CDER, FDA

Edward Patten, MS
Associate Director for Manufacturing Science
CBER, FDA

Melissa Burns, MS
Senior Program Manager
CDRH, FDA

Francisco Vicenty
Supervisory Consumer Safety
CDRH, FDA

Rakhi Dalal Panguluri
Toxicologist
CDRH, FDA

Melissa Torres
Acting Deputy Director
Division of Cardiovascular Devices
CDRH, FDA

James Dunnie
Consumer Safety Officer
ORA, FDA

John (Barr) Weiner, JD
Associate Director for Policy and Product Classification Officer
Office of Combination Products, FDA

3:15-3:45PM REFRESHMENT AND NETWORKING BREAK

3:45-5:15PM SESSION 4: COLLABORATION IN THE INDUSTRY

SESSION CO-CHAIRS:

James Boiani, JD, MS
Senior Counsel
Epstein Becker Green

Winifred Wu, MBA, FRAPS
President and Principal Advisor
Strategic Regulatory Partners, LLC

Developing combination products often requires collaboration between drug, device, and biological product manufacturers. Partner relationships can range from joint development/joint ventures to working with key suppliers, to co-marketing. Business development professionals will share their best practices and challenges when collaborating with business partners. In this session, attendees will hear several scenarios of the diverse types of collaboration through presentations from multiple companies.

SPEAKERS:

Collaboration in the Industry

Aaron Kemp
Senior R&D Manager
BD Medical

Coordinating Quality Systems with Partners

Kirsten Paulson, MS
Senior Director
Global CMC - Medical Devices
Pfizer, Inc.

Managing Successful Partnerships: From Novel Therapy Development Through Commercialization

Brenda Schultz
Alliance Manager
Medtronic

Building Strong Technical Relationships: A Lifelong Commitment

Sandy Koppenol
Senior Research Scientist II
Gilead Sciences

Supplier Selection Process for Devices in Combination Products

Christopher Kurtz
Vice President
Drug Device Industrialization
AbbVie

5:15-6:15PM NETWORKING RECEPTION

TUESDAY, SEPTEMBER 29

7:30AM-12:00PM **REGISTRATION**

7:30-8:30AM **CONTINENTAL BREAKFAST**

8:30-10:00AM SESSION 5: HUMAN FACTORS REVIEW FOR COMBINATION PRODUCTS

SESSION CHAIR:

Kirsten Paulson, MS, RAC
Senior Officer, Medical Device Initiative
Pfizer, Inc.

FDA reviewers will discuss their experiences with review of human factors study protocols and common misconceptions or deficiencies. Discuss how FDA coordinates review of Instructions for Use with IFU validated through usability testing, and varying human factors expectations between FDA Centers.

Human Factors Issues in Combination Products – A Case Study

PANELISTS:

Patricia Love, MD, MBA
Deputy Director
Office of Combination Products, OSPM, OMPT, FDA

Irene Chan, PharmD
Director
Division of Medication Error Prevention and Analysis
CDER, FDA

Kathleen O'Sullivan
Associate Director, Regulatory Affairs
BD Medical-Pharmaceutical Systems

Shannon Hoste, MS
Human Factors Pre-Market Evaluation Team Member
CDRH, FDA

10:00-10:30AM **REFRESHMENT AND NETWORKING BREAK**

10:30AM-12:00PM SESSION 6: GLOBAL UPDATES

SESSION CO-CHAIRS:

James Boiani, JD, MS
Senior Counsel
Epstein Becker Green

Winifred Wu, MBA, FRAPS
President and Principal Advisor
Strategic Regulatory Partners, LLC

Drug and Device Regulators from the EU will provide an update on the current environment for combination product approval requirements and share their insights. This session will include presentations from representatives from a Notified Body (BSI) and a Competent Authority, Medicines and Healthcare Products Regulatory Agency (MHRA) followed by Q&A.

EU Regulations and Approval Process for Device/Drug Products

SPEAKERS:

Elizabeth Baker
Group Manager Licensing Division
MHRA

Ibim Tariah, PhD
Technical Director, Healthcare
BSI Group America Inc.

12:00-1:00PM **LUNCHEON AND NETWORKING**

1:00-2:30PM **SESSION 7: ROUNDTABLE DISCUSSIONS**

SESSION CHAIR:

Dave Anderson
Associate Director - Quality for Combination Products
AstraZeneca Biologics (MedImmune)

This session will be a highly interactive activity with several tables of 5-10 participants actively discussing a timely topic of interest, followed by a brief summary report out from each table at the end of the session. A subject matter expert will be assigned to each table to guide the discussion, and special focus will be on experiences and lessons learned.

Pediatric Indications and PREA Requirements

MODERATOR:

Kirsten Paulson, MS, RAC
Senior Director
Global CMC - Medical Devices
Pfizer, Inc.

The Pediatric Research Equity Act of 2003 (PREA) requires that pediatric studies be conducted for any new application (NDA, BLA, or supplement) that provides a new indication, new dosage form, new dosing regimen, or new route of administration (unless the requirement is waived or deferred). This discussion will focus on the PREA implications for combination products.

Total Product Life Cycle: Life Cycle Management of Combination Products

MODERATOR:

Winifred Wu, MBA, FRAPS
President and Principal Advisor
Strategic Regulatory Partners, LLC

The "care and feeding" of combination products throughout their product life cycle requires much coordination, especially if multiple organizations are involved with different constituent parts. Close coordination between different organizations is needed, e.g. in post-approval changes and adverse event reporting. FDA published a proposed rule in 2009 on postmarket safety reporting for combination products. The discussants will highlight current practices and identify challenges in coordinating post-approval changes and safety reporting.

Risk Management for Combination Products

MODERATOR:

Kathleen O'Sullivan, MS, RAC
Associate Director, Regulatory Affairs
BD Medical Pharmaceutical Systems

Quality risk management (QRM) is important in ensuring quality throughout the entire product lifecycle, and is recommended by FDA and other regulating agencies. Risk management for combination products already on the market as well as those entering the market can present unique challenges, especially when formal documentation does not exist that meet current QRM expectations (e.g., pFMEA, dFMEA, etc.). Considerations for QRM of combination products will be discussed.

Combination Therapies

MODERATOR:

Dave Anderson
Associate Director – Quality for Combination Products
AstraZeneca Biologics (MedImmune)

Treatment of a disease or condition with combinations of drugs, biologics, and devices together continues to evolve and become more important, especially in oncology therapy. For example, innovative advances are occurring in nanobiotechnology, where new products and concepts integrate unique biological, chemical and mechanical entities and properties at very small scales. This discussion will explore any special co-development and regulatory challenges for combination therapies as combination products in marketing applications.

Generic/Biosimilars in Combination Products

MODERATOR:

Willy Liou, MS, RAC
Manager, Regulatory Affairs
Amgen, Inc.

Generics/biosimilars can be used in combination therapies, and FDA has provided insight on these in combination products in recent question and answer documents. For biosimilars, some design differences in a delivery device or container closure system, compared to the originator, are potentially acceptable, and this group will discuss development and commercial implications.

2:30-3:00PM **REFRESHMENT AND NETWORKING BREAK**

3:00 – 4:30PM **SESSION 8: ASK THE REGULATORS**

MODERATOR:

Steven Binion, PhD, MBA
Director
Policy, Technology and Communication
Corporate Regulatory Affairs
Becton Dickson

Join this final session for a unique chance to meet with senior leadership from FDA and foreign regulators and ask questions regarding current issues and opportunities in the regulation of combination products in an open and interactive session.

PANELISTS:

Elizabeth Baker
Group Manager Licensing Division
MHRA

Patricia Love, MD, MBA
Deputy Director
Office of Combination Products, OSPM, OMPT, FDA

William Maisel
Deputy Director for Science
Chief Scientist
CDRH, FDA

Diane Maloney, JD
Associate Director for Policy
CBER, FDA

Thinh Nguyen, PhD
Director
Office of Combination Products, FDA

Douglas Throckmorton, MD
Deputy Center Director for Regulatory Programs
CDER, FDA

John (Barr) Weiner, JD
Associate Director for Policy and Product Classification Officer
Office of Combination Products, FDA

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