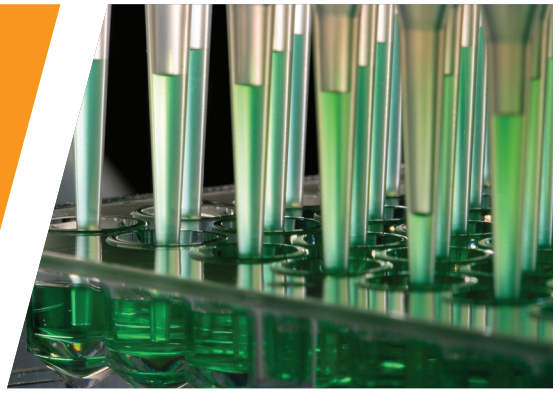
DIA Meeting on Combination Products

November 5 | Alexandria, VA



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Jennifer Paine
Worldwide VP of Quality
Regulatory and Compliance
Ortho Clinical Diagnostic -
Part of the Johnson & Johnson Family of Companies

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Corporate Regulatory/Women's Health and Cancer
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Bradley Merrill Thompson, JD, MBA
Partner
Epstein, Becker and Green P.C.

John (Barr) Weiner, JD
Associate Director for Policy and
Product Classification Officer
OCP, FDA

Register at
diahome.org/CombinationProducts

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OVERVIEW:

Advances in scientific knowledge and technology are driving growth and innovation for combination products and companion diagnostics, thereby enabling personalized therapies that:

- target those patients most likely to benefit from treatment;
- exclude those patients most likely to suffer harm; and
- can be monitored during treatment for clinically significant changes.

This meeting will provide a practical approach to development processes and regulations in these evolving landscapes, and will focus on combination products.

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Because combination products involve components that would normally be regulated under different types of regulatory pathways, and frequently by different FDA Centers, they raise challenging policy, regulatory, and review management challenges. Differences in pathways ordinarily associated with each component can raise questions for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

This day will focus on:

- Innovation in Combination Products
- Development Challenges, Preclinical and Clinical Data, and Human Factor Considerations for Combination Products
- Infrastructure to Support Combination Products
- Regulatory Developments

LEARNING OBJECTIVES:

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

- Discuss the US regulatory framework for drug/device combination products development and registration
- Describe the differences between device and drug development processes and regulations
- Identify key challenges facing combination product developers as well as potential options to address these challenges
- Discuss the current status and emerging issues in the EU

DIA is hosting a related one-day meeting on personalized medicines and their companion diagnostics, November 6: DIA Meeting on Personalized Medicines and Companion Diagnostics.

Register for Both Meetings and Save!

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- Clinical Research Certificate Program: 4 Elective Units
- Regulatory Affairs Certificate Program: 4 Elective Units

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TUESDAY, NOVEMBER 5

7:30-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:20 AM WELCOME AND OPENING REMARKS

Jennifer Paine
Worldwide VP of Quality
Regulatory and Compliance
Ortho Clinical Diagnostic

8:20-8:35 AM KEYNOTE ADDRESS

David Dorsey
Senior Director, Americas Head
Global Regulatory Policy and Intelligence
Janssen Research and Development

8:35-9:00 AM SESSION 1

Combination Products State of the Union

Session Chair/Speaker

Thinh X. Nguyen
Director
OCP, FDA

9:00 AM-10:30 PM SESSION 2

Development Challenges, Preclinical and Clinical Data and Human Factor Considerations for Combination Products

Session Chair

James A. Boiani, JD, MS
Senior Associate
Epstein Becker Green

Combination products increasingly incorporate both new technologies and novel marriages of drugs, biologicals, and medical devices. These products hold great promise, but bringing them to patients can challenge industry and regulators as they try to answer important questions about product safety and effectiveness. Nowhere is this more apparent than with combinations of drugs and biologicals with new delivery systems. This session will explore the challenges in developing combination products with a focus on drug/biological delivery systems, preclinical and clinical combination product data requirements, and human factor testing. FDA thought leaders will provide Agency perspectives, and industry experts will discuss their experiences in navigating these issues.

Recent Development in Drug Delivery Systems

Patricia Y. Love
Deputy Director
OCP, FDA

Richard McFarland
Medical Officer, OCTGT
CBER, FDA

Human Factor Studies and Data Bridging Issues

Valerie Fenster
Senior Manager
Human Factors Engineering
Amgen

Industry Perspective on Combination Product Development

Hortense Allison
Senior Manager
Regulatory Affairs
Johnson & Johnson's Visioncare

Panel Discussion

10:30-11:00 AM REFRESHMENT BREAK

11:00-12:30 PM SESSION 3

Combination Products CGMP

Session Chair

Steven B. Binion, PhD, MBA
Director
Corporate Regulatory Affairs/Women's Health and Cancer
Becton, Dickinson and Company

FDA issued the Current Good Manufacturing Practice (CGMP) Requirements for combination products to promote 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 organizations to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products. In this session, FDA will outline the final rule, discussing the requirement and expectations. Much of the session will be designed to provide an opportunity for audience participants to interact directly with CDER, CDRH, CBER and OCP.

CGMP Final Rule

John B. Weiner, JD
Associate Director
Policy and Product Classification Officer
OCP, FDA

Industry Perspectives

Alex Wesolowski
Vice President
Corporate Regulatory Affairs
Becton, Dickinson and Company

Jeanmarie Sales
Distinguished Regulatory Affairs Advisor
Medtronic, Inc., Neuromodulation

CDER, CDRH and CBER Perspective

Edward Patten
Associate Director
Manufacturing Science
CBER, FDA

Steven Hertz
Consumer Safety Officer
CDER, FDA

M. Isabel Tejero del Rio, MD, PhD
Consumer Safety Officer
CDRH, FDA

Melissa Torres
Supervisory Biomedical Engineer
Office of Device Evaluation
CDRH, FDA

Panel Discussion

12:30-1:30 PM LUNCHEON

1:30-3:00 PM SESSION 4

Global Development

Session Chair

Jennifer Paine
Worldwide Vice President
Regulatory Affairs
Ortho Clinical Diagnostic

As the market for global drug device combination products is expected to reach $30 billion by 2014, understanding international access challenges and regulatory changes is essential. In particular, changes to the Medical Device Directive in the EU will impact combination product oversight, and globally there are differences in how combination products are viewed by regulators. This session will provide overviews and insight into regulatory requirements and expectations of global markets.

Bridging

Erik Vollebregt
Partner
AXON Lawyers

Multi-market Access Challenges

Elizabeth Baker
Group Manager
Licensing Division
MHRA, UK

EU Regulatory Changes

Paul Brooks
Vice President
BSI Healthcare

Panel Discussion

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM SESSION 5

Use of Mobile Medical Applications as Companions

SESSION CHAIR

Bradley Merrill Thompson, JD
Combination Products Coalition

FDA has predicted that it will come out with a final guidance on mobile medical apps by October 1. This session will explore that final guidance, teasing apart exactly what types of apps in the pharmaceutical space will be regulated and which ones will not. To make the session more dynamic, we will explore several pre-prepared case studies that focus squarely on the difficult issues associated with applying that guidance to the pharmaceutical use cases. Three commentators will provocatively discuss the different possible interpretations of the guidance as applied to the case studies, and then we will ask the audience, using an electronic polling system, to vote to put the technology at issue into one of the following four categories: a.) Unregulated mobile app; b.) FDA regulated drug labeling; c.) FDA regulated medical device; or d.) FDA regulated medical device constituent part of a combination product. After seeing the audience poll, the panel will discuss whether they agree with the audience's assessment.

FDA Regulation of Mobile Apps

Bradley Merrill Thompson, JD
Combination Products Coalition

Case Studies & Audience Interaction

Mary Ann Smith
DRA Policy Head
Medical Device and Combination Products
Novartis

Azin Shahzamani
Senior Director
Regulatory Affairs
Genentech

Jafar Shenasa
Senior Director
Regulatory Affairs
Proteus Digital Health, Inc.

5:00-5:15 PM CLOSING REMARKS

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