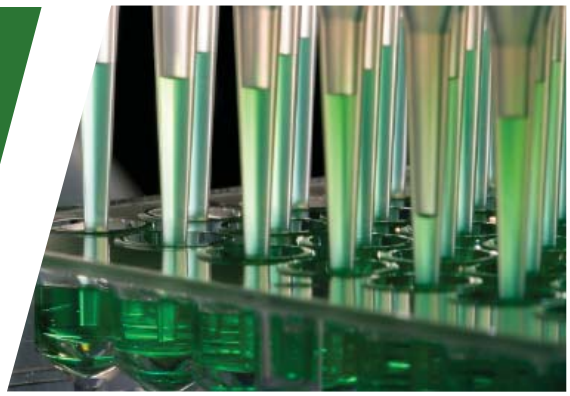
DIA WORKSHOP:

Regulatory Considerations for Drug/Device Combinations and Companion Diagnostics

November 7-8 | Westin Washington DC City Center



CHAIRPERSON

Jennifer Paine
WW Vice President of Regulatory Affairs
Ortho Clinical Diagnostic
(Part of the Johnson & Johnson family of companies)

PROGRAM COMMITTEE

Kristina J. Lauritsen, PhD
Senior Scientific Reviewer
Office of Combination Products, FDA

Amy M. Miller, PhD
Vice President, Public Policy
Personalized Medicine Coalition

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Senior Director
Regulatory Affairs
Genentech
(A Member of the Roche Group)

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CDRH, FDA

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MEETING OVERVIEW

FDA expects to receive large numbers of combination products for review as technological advances continue to merge product types and blur the historical lines of separation between FDA's medical product centers. 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, scientific, and review management issues. Differences in regulatory pathways for each component can impact the regulatory processes 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 postapproval modifications.

This two-day conference will provide you with an understanding of the regulatory frameworks for drug/device combinations and drug/diagnostic pairs. It will focus on the differences between device and drug development processes and regulations, and will highlight regulatory challenges facing developers and manufacturers. FDA will provide updates on regulatory developments and guidance.

How will this meeting meaningfully talk about such a diverse topic as combination products? The workshop will provide an overview of combination products, general principles, and pre- and postmarket considerations. A deeper delve into companion diagnostics will wrap up this interactive conference.

SESSION TOPICS

- Overview of regulatory framework for combination products
- Regulatory developments for combination products and companion diagnostics
- Developmental challenges for therapeutic drug/device and combination products and drug/diagnostic pairs
- Matching drugs and devices for breakthrough therapies
- Cross labeling
- New technologies
- Panel discussions, case studies, and interactive sessions

WHO SHOULD ATTEND

- Pharmaceutical, academic and government senior-level professionals and decision-makers involved in drug development and R&D
- Pharmaceutical and medical device and diagnostics professionals
- Regulatory, clinical and other professionals responsible for developing drug/device combinations and companion diagnostics
- Regulatory affairs professionals

In Collaboration with

PMC Personalized Medicine Coalition

MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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CONTINUING EDUCATION

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer 1.1 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through DIA's My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Wednesday, November 21, 2012.

This program is part of DIA's Certificate Program and is awarded the following:

- Regulatory Affairs Certificate Program: 7 Elective Units

For more information go to www.diahome.org/certificateprograms

Disclosure Policy
It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Learning Objectives
At the conclusion of this conference, participants should be able to:
- Discuss the regulatory frameworks for drug/device combinations and drug/diagnostic pairs
- Describe the differences between device and drug development processes and regulations
- Identify regulatory challenges facing developers and manufacturers

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association. Speakers, agenda and CE information are subject to change without notice.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at **www.diahome.org**.

DAY 1 | WEDNESDAY, NOVEMBER 7, 2012

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

8:30-8:35 AM WELCOME AND OPENING REMARKS

Jennifer Paine
WW Vice President of Regulatory Affairs
Ortho Clinical Diagnostic
(Part of the Johnson & Johnson family of companies)

8:35-9:00 AM KEYNOTE ADDRESS

Stephen P. Spielberg, MD, PhD
Deputy Commissioner for Medical Products and Tobacco
FDA

9:00-9:30 AM SESSION 1

Combination Product Overview

Session Chair

Thinh X. Nguyen
Director
Office Combination Products, FDA

This presentation will set the stage for this workshop by outlining taxonomy and providing a chronological overview of combination products. The session will also focus on process, from classification and assignment to premarket review and postmarket regulation. Landscape and recent regulatory activity will also be reviewed.

9:30-10:30 AM SESSION 2, PART I

Combination Product Premarket Considerations

Session Co-chairs

Nancy Stade, JD
Deputy Director for Policy
CDRH, FDA

Douglas C. Throckmorton, MD
Deputy Director, Regulatory Programs
CDER, FDA

From what kind of product you have to how it's assigned, to application development and review, the pre-market steps will be discussed. Classification and assignment challenges will be reviewed. Interactive case studies and scenarios will bring these steps together.

Regulatory Perspective
Kristina J. Lauritsen, PhD
Senior Scientific Reviewer
Office of Combination Products, FDA

Regulatory Case Studies
Kathy Lee
Lead for Interdisciplinary Science
Division of Therapeutic Proteins, Office of Pharmaceutical Science
Office of Biotechnology Products
CDER, FDA

Ashley Boam
Acting Associate Director for Regulations and Guidance
Office of Device Evaluation
CDRH, FDA

10:30-11:00 AM REFRESHMENT BREAK

11:00 AM-12:00 PM SESSION 2, PART II

Combination Product Premarket Considerations (continued)

Industry Perspective: Working with FDA on Combination Products
Winifred C. Wu, MBA, FRAPS
President
Strategic Regulatory Partners, LLC

Trade Association Perspective
Heather Rosecrans
Vice President of Regulatory Affairs
MDMA

Attorney Perspective
David M. Fox
Partner
Hogan Lovells US LLP

12:00-1:00 PM LUNCHEON

Attendees are encouraged to submit questions during lunch for Part III, the Panel Discussion

1:00-1:30 PM SESSION 2, PART III

Combination Product Premarket Considerations (continued)

Panel Discussion

1:30-3:00 PM SESSION 3, PART I

Combination Product Postmarket Considerations

Session Chair
Jennifer Paine
WW Vice President of Regulatory Affairs
Ortho Clinical Diagnostic
(Part of the Johnson & Johnson family of companies)

This session will provide a general framework of postmarket considerations. Application of drug and device statutory and regulatory requirements to combination products will also be reviewed.

GMPs
Michael Gross, PhD, RAC
Principal Consultant
Chimera Consulting North America LLC

FDA Perspective on Inspections
Steven Hertz
Senior Consumer Safety Officer
Office of Manufacturing and Product Quality
Division of Good Manufacturing Practice Assessment
CDER, FDA

Adverse Event Reporting
Leighton Hansel
Director, Regulatory Affairs
Abbott Quality & Regulatory

3:00-3:30 PM REFRESHMENT BREAK

3:30-4:30 PM SESSION 3, PART II

Combination Product Postmarket Considerations (continued)

Postmarket Changes
Danelle Miller
Regulatory Counsel
Roche Diagnostics

FDA Perspective
John B. Weiner, JD
Associate Director for Policy
Office of Combination Products, FDA

Panel Disussion and Questions

4:30 PM DAY ONE ENDS

DAY 2 | THURSDAY, NOVEMBER 8, 2012

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

8:30-8:50 AM SESSION 4

Companion Diagnostics Overview

SESSION CHAIR

Elizabeth Mansfield
Director of Personalized Medicine
Office of In Vitro Diagnostic Device Evaluation and Safety, FDA

This presentation will provide an evolutionary overview of companion diagnostics and taxonomy.

8:50-10:30 AM SESSION 5

Companion Diagnostics Development

SESSION CHAIR

Michael A. Pacanowski, PharmD, MPH
Team Lead for Genomics
Office of Clinical Pharmacology
CDER, FDA

This session will be devoted to the definition of diagnostics versus companion diagnostics and an evaluation of whether the paths are the same or whether there are different considerations with companion diagnostics.

Business Case for Personalized Medicines
Mark Trusheim
President at Co-Bio Consulting, LLC
Executive in Residence & Visiting Scientist at MIT

Regulatory Framework and Labeling
Michael A. Pacanowski, PharmD, MPH
Team Lead for Genomics
Office of Clinical Pharmacology
CDER, FDA

Companion Diagnostic Device Development and Regulatory Pathways
Robert L. Becker Jr, MD, PhD
Office of In Vitro Diagnostic Device Evaluation and Safety
CDRH, FDA

Panel Discussion
Estelle Russek-Cohen, PhD
Acting Division Director
Division of Biostatistics, Office of Biostatistics and Epidemiology
CBER, FDA

10:30-10:45 AM REFRESHMENT BREAK

10:45 AM-12:30 PM SESSION 6

Current Challenges in Companion Diagnostics

SESSION CHAIR

Azin Shahzamani
Senior Director
Regulatory Affairs
Genentech
(A Member of the Roche Group)

This session will focus on the current challenges in companion diagnostics. Challenges in clinical trial design, biomarker development and validation, and drug and diagnostics timing will be covered.

Premarket Biomarker Development and Validation: Drug Developer Perspective
Shirin Khambata Ford, PhD
Executive Director
Global Head, Oncology Correlative Sciences
Novartis Pharmaceuticals Corporation

Challenges in Clinical Trial Design
Jeffrey Siegel, MD
Senior Group Medical Director
Product Development Immunology
Genentech, Inc.

Drug and Diagnostic Timing: Device Developer Perspective
Eric W. Kolodziej, PhD, MBA
Senior Vice President, Global Regulatory Affairs
Roche Diagnostics Operations

Panel Discussion
Jay P. Siegel, MD
Chief Biotechnology Officer and Head
Global Pharmaceutical Regulatory Affairs
Johnson & Johnson
Head of Pharmaceutical Global Regulatory Affairs
Janssen

12:30-1:30 PM LUNCHEON

1:30-2:55 PM SESSION 7

Looking Forward

SESSION CHAIR

Jill Hartzler Warner, JD
Acting Associate Commissioner for Special Medical Programs
FDA

What issues need further attention? This session will focus on the future of combination products and companion diagnostics. Consistency, efficiency, predictability, and transparency will be a focus of this interactive panel discussion. Topics include the payer perspective on postmarket implementation challenges, public policy update and challenges, and the legal perspective.

Panel Discussion

John Carlsen, MHA
Vice President
Covance Market Access Services Inc.

Elizabeth Mansfield
Director of Personalized Medicine
Office of In Vitro Diagnostic Device Evaluation and Safety, FDA

Amy M. Miller, PhD
Vice President, Public Policy
Personalized Medicine Coalition

Nancy Stade, JD
Deputy Director for Policy
CDRH, FDA

Bradley Merrill Thompson, JD
Combination Products Coalition

Douglas C. Throckmorton, MD
Deputy Director, Regulatory Programs
CDER, FDA

John B. Weiner, JD
Associate Director for Policy
Office of Combination Products
FDA

2:55-3:00 PM WRAP UP

Minnie Baylor-Henry, JD, RPh
DIA President Elect
Worldwide Vice President, Regulatory Affairs
Johnson & Johnson Medical Devices & Diagnostics

3:00 PM WORKSHOP ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

DIA Workshop: Regulatory Considerations for Drug/Device Combinations and Companion Diagnostics

Event #12016 • November 7-8, 2012

Westin Washington DC City Center | Washington, DC

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Member Early-bird Opportunity Available on nondiscount member fee only	On or before OCT. 17, 2012	After OCT. 17, 2012
Member Fee	US $1340 ❑	US $1490 ❑

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To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee US $1665 ❑

A one-year membership to DIA is available to those paying a nonmember registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER
Government (Full-time)	US $595 ❑	US $770 ❑
Charitable Nonprofit/Academia (Full-time)	US $745 ❑	US $920 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

TO RECEIVE A TABLETOP EXHIBIT APPLICATION, PLEASE CHECK ❑

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible. The Westin is holding a block of rooms at the reduced rate below until October 16, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $239 Double $239

Attendees must make their own hotel reservations. Contact the Westin by telephone at +1.202.429.1700 and mention the DIA event. The hotel is located at Westin Washington DC City Center, 1400 M St., NW Washington, DC 20005.

CANCELLATION POLICY: On or before OCTOBER 31
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for canceling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is canceled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

CONTACT INFORMATION

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email **Marilyn.Ginsberg@diahome.org**

TABLE TOP EXHIBIT INFORMATION

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