Marketing Pharmaceuticals 2016

Tutorial: March 2 | Conference: March 3–4 | Bethesda North Marriott Hotel and Conference Center | Bethesda North, MD

PROGRAM COMMITTEE:

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

Glenn Byrd, MBA, RAC
Senior Director
Promotional Regulatory Affairs
AstraZeneca Specialty Care

Dale Cooke
Owner
PhillyCooke Consulting

Mark Gaydos
Vice President and Head
US Specialty Care 2
Head
US Advertising and Promotion Center of Excellence
North America and Global Regulatory Affairs
Sanofi

Lyn Hopkinson, BPharm
VP Commercial Regulatory Affairs
Global Regulatory Affairs
Vertex Pharmaceuticals Incorporated

John Murray
President
Grayscale Compliance LLC

Wayne L. Pines
President
Regulatory Services and Healthcare
APCO Worldwide Inc.

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Kristina Vlaovic, MPH
Vice President, Regulatory, Safety and Pharmacovigilance
HALOZYME Inc.

Overview

Now in its 27th year, the DIA Marketing Pharmaceuticals 2016 Program Committee created a program that celebrates the conference components you look forward to each year while increasing the number of varied content offerings, introducing new interactive session formats, and providing more structured networking opportunities.

Who Should Attend

Professionals in pharmaceutical, biologics, and medical device companies involved in:

- Regulatory Affairs
- Marketing
- Communications
- Compliance
- Medical Information and Affairs Legal
- Senior Management

Highlights

- Tabletop Exhibits in Grand Ballroom Salon D
- Question and Answer Session with FDA - pick up a question card from the registration desk

New This Year

- Meet members from DIA's Regulatory Affairs Ad Promo (APWG) community and learn how to get involved.
  - Wednesday, March 2 from 5:15PM–6:30PM APWG Face-to-face meeting in the Forest Glen meeting room
  - Friday, March 4 at 8:00AM Kim Belsky, APWG Co-chair, will be giving a presentation on the APWG's membership and project updates during the opening remarks.
- Luncheon Round Table Discussions with Community Leaders on March 4, 11:30AM-1:00PM
- View Poster Presentations throughout the conference in Grand Ballroom Salon D
- More interactive sessions to learn from industry experts and your peers through panel and audience discussions

Medical Affairs and Scientific Communications 2016 Annual Forum

Highlights

- FDA Update and Potpourri
- Policy and Medicine
- New Drugs of 2015 Review
- Demonstrating and Communicating the Value of Medicines Through Health Economic and Outcomes Evidence

Core Curriculum: March 20

Tutorials (AM): March 21

Forum: March 21-23

Gaylord Palms Resort and Convention Center

Kissimmee, FL

Experience the Conference on the Go with the DIA Global App

Download the DIA Global app to view the agenda and speakers, network with attendees and exhibitors, and get updates throughout the conference.

Search "DIA Global" in your app store.

TO ACCESS PRESENTATIONS:

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Schedule At-A-Glance

P Interactive panel discussion A Facilitated audience discussion

TUTORIAL | WEDNESDAY, MARCH 2

1:30–5:00PM	Tutorial: OPDP/APLB 101: A Primer Based on Today's Changing Environment

DAY ONE | THURSDAY, MARCH 3

7:30AM–6:00PM	Registration
7:30–8:30AM	Continental Breakfast, Exhibits, and Networking
8:30–8:45AM	Welcome Remarks
8:45–10:30AM	Session 1: Ad-Promo Litigation: Amarin and Beyond P
10:30–11:00AM	Refreshment Break, Exhibits, and Networking
11:00AM–12:30PM	Session 2: Engaging Payers, Nontraditional, and Emerging Customer Markets P
12:30–1:30PM	Luncheon, Exhibits, and Networking
1:30–3:00PM	Session 3: Breakout Sessions
	Session 3A: Safety Labeling Changes — Real-World Execution into Packaging, Advertising and Promotion, and Beyond A
	Session 3B: Global Promotion Review Process and Standards
	Session 3C: Mock Review: A Regulatory Perspective A
3:00–3:30PM	Refreshment Break, Exhibits, and Networking
3:30–5:00PM	Session 4: Breakout Sessions
	Session 4A: Safety Labeling Changes — Real-World Execution into Packaging, Advertising and Promotion, and Beyond A
	Session 4B: Global Promotion Review Process and Standards
	Session 4C: Mock Review: A Regulatory Perspective A
5:00–6:00PM	Poster Session and Networking Reception

DAY TWO | FRIDAY, MARCH 4

7:00AM–4:00PM	Registration
7:00–8:00AM	Continental Breakfast, Exhibits, and Networking
8:00–8:05AM	Welcome to Day Two
8:05–9:35AM	Session 5: FDA Update: Recent Enforcement Actions and Guidances
9:35–10:00AM	Refreshment Break, Exhibits, and Networking
10:00–11:30AM	Session 6: Using New and Emerging Technologies Compliantly
11:30AM–1:00PM	Luncheon Round Table Discussions and Exhibits
1:00–2:10PM	Session 7: Breakout Sessions
	Session 7A: Scientific Exchange and the Responsible Sharing of Truthful and Non-Misleading Information About Medicines with HCPs A
	Session 7B: Advocacy Groups: When and How Should They Be Engaged?
	Session 7C: Review Standards for Ad Boards and Consultant Meetings
2:10–2:30PM	Refreshment Break, Exhibits, and Networking
2:30–3:30PM	Session 8: Compliance Update Panel P
3:30–4:00PM	Closing Session: Question and Answer with FDA P

Learning Objectives

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

- Identify the trends reflected in the latest enforcement actions and policies issued by the FDA
- Examine the compliance challenges companies face, including how to evaluate challenges, and factors to consider that may impact the development of solutions
- Discuss the best US and global review and approval practices
- Describe promotional and non promotional tactics trending in the pharmaceutical industry that require thoughtful regulatory review
- Analyze effective digital and social media strategies designed to meet the challenges of ensuring compliance with FDA regulatory requirements

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 13.75 contact hours or 1.375 continuing education units (CEU's). Type of Activity: Knowledge

ACPE Credit Requests MUST BE SUBMITTED by Monday April 18, 2016. DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript **within 45-days post** activity. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net.**

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET). As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.5 CEUs for this program. Participants must attend the entire program (and tutorial(s), if applicable) 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 conference (tutorial, if applicable; sign in at the registration desk), complete the "Verification of Attendance" form located in your conference folder, turn in your form to the registration desk at the conclusion of the conference, and complete the online credit request process through My Transcript. 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 **Friday, March 18, 2016**.

To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the forum

The evaluation closes on Friday, March 25, 2016.

View DIA's Grievance Policy at **DIAglobal.org/CE**

Continuing Education Credit Allocation

Tutorial: OPDP/APLB 101: A Primer Based on Today's Changing Environment: IACET: .3 CEUs; Pharmacy: 3.25 contact hours or .325 CEUs, 0286-0000-16-010-L04-P

Conference: IACET: 1.2 CEUs

Pharmacy Credit Allocation:

- Welcome and Session 1: 2 contact hours or .2 CEUs, 0286-0000-16-011-L04-P
- Session 3A: Safety Labeling Changes: 1.5 contact hours or .15 CEUs, 0286-0000-16-012-L05-P
- Session 3C: Mock Review: A Regulatory Perspective: 1.5 contact hours or .15 CEUs, 0286-0000-16-013-L04-P
- Session 4A: Safety Labeling Changes: 1.5 contact hours or .15 CEUs, 0286-0000-16-014-L05-P
- Session 4C: Mock Review: A Regulatory Perspective: 1.5 contact hours or .15 CEUs, 0286-0000-16-015-L04-P
- Sessions 5 and 6: 3 contact hours or .3 CEUs, 0286-0000-16-016-L04-P
- Session 7A: Scientific Exchange: 1 contact hour or .1 CEU, 0286-0000-16-017-L04-P
- Session 7B: Advocacy Groups: 1 contact hour or .1 CEU, 0286-0000-16-018-L04-P
- Session 7C: Review Standards: 1 contact hour or .1 CEU, 0286-0000-16-019-L04-P
- Session 8: Compliance Update Panel and Closing Session: 1.5 contact hours or .15 CEUs, 0286-0000-16-020-L04-P

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosure statements will be included in the meeting materials.

DIA'S CERTIFICATE PROGRAM

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

- Regulatory Affairs Certificate Program: 8 Elective Units

For more information go to **DIAglobal.org/certificateprograms**

WEDNESDAY, MARCH 2

1:30–5:00PM

Half Day Tutorial – OPDP/APLB 101: A Primer Based on Today's Changing Environment

Instructors:

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Michele Sharp, PharmD
Senior Director, Global Regulatory Affairs – US
Eli Lilly and Company

If you are new, or relatively new, to the preparation or review of advertising and/or promotional materials, this tutorial is for you! This tutorial is designed to provide background information for you to better understand the conference content. The leaders will provide an introductory foundation for anyone working in our current regulatory environment. Whether you are a regulatory, legal, medical, compliance, or marketing professional, the information will be interesting, practical, and vital.

Learning objectives

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

- Discuss the current regulatory/compliance environment pertaining to prescription drugs, biologics, and medical devices as relevant to the DIA program content
- Describe the FDA advertising and promotional requirements, including such topics as (as relevant to the final program content): claim support requirements, fair balance expectations, internet and social media challenges, product booths at medical conventions, adherence and preference programs, patient involvement and outreach, disease state programs, and public relations challenges

THURSDAY, MARCH 3

7:30AM–6:00PM Registration

7:30–8:30AM Continental Breakfast, Exhibits, and Networking

8:30–8:45AM

Welcome Remarks

Raleigh Malik, PhD
Senior Scientific Liaison, Americas
DIA

Wayne L. Pines
President
Regulatory Services and Healthcare
APCO Worldwide Inc.

8:45–10:30AM

Session 1: Ad-Promo Litigation: Amarin and Beyond

Session Chair:

Douglas H. Hallward-Driemeier
Partner
Ropes & Gray, LLP

Recent litigation, such as the Amarin and Pacira cases, raise far reaching new issues about the regulatory policies for the advertising and promotion of prescription products. Is a paradigm shift coming? How will the FDA and Congress address these issues? Is still more litigation on the horizon? What should individual companies do right now? This session will provide a brief background on these cases, but focus on the policy and day-to-day practical implications of this litigation.

Panelists:

Jeff Handwerker
Partner
Arnold & Porter, LLC

Michael Listgarten
Senior Associate General Counsel
Genentech, Inc., A Member of the Roche Group

John Fleder
Director
Hyman, Phelps & McNamara

10:30–11:00AM Refreshment Break, Exhibits, and Networking

11:00AM–12:30PM

Session 2: Engaging Payers, Nontraditional, and Emerging Customer Markets

Session Chair:

John Murray
President
Grayscale Compliance LLC

The rapid evolution of health care coverage and payment has led to an increase in unique customers and sales and marketing strategies. Employers, government and private health plans, purchasing groups, retail pharmacies, specialty pharmacies, institutions, and patients themselves are all sharing in the financial landscape of prescription drugs and biologics. A panel of regulatory, legal, and commercial experts will discuss payer and access marketing programs and strategies as well as some of the unique regulatory and legal issues.

Panelists:

William Sarraille
Partner
Sidley Austin LLP

Eric Toppy
Chief Commercial Officer
Ethos Health Communications

Scott Dulitz, MBA
Vice President of Market Access Solutions
TrialCard

12:30–1:30PM Luncheon, Exhibits, and Networking

1:30–3:00PM **Session 3: Breakout Sessions**

Session 3A

Safety Labeling Changes: Real-World Execution into Packaging, Advertising and Promotion, and Beyond

Session Chair:

Sandra Kerr, RPh
Executive Director, Office of Promotion and Advertising Review
Merck & Co., Inc.

The Food and Drug Administration Amendments Act (FDAAA) of 2007 authorizes FDA to require labeling changes when it becomes aware of new safety information it believes should be included in the labeling of an approved drug product. However, neither the statute nor the draft guidance include specific deadlines or timeframes for how quickly the revised labeling must be incorporated into the packaging of the product or into other labeling such as promotional labeling. Sponsor initiated safety changes such as Changes Being Effected (CBE) supplements have no mandatory timeframes for review and/or action by the agency or timelines for implementation. This session will review the regulations, guidance, and proposed rules related to implementing safety labeling changes. It will also give you the opportunity to work through case studies with others in industry and discuss best practices and considerations for successful implementation of revised labeling.

Facilitators:

Kim Belsky, MS
Executive Director
OneSource Regulatory

Dolores Shank-Samiec, MS
Director Office of Promotion and Advertising Review
Merck & Co., Inc.

Kelly Treonze
Director, Worldwide Product Labeling
Merck & Co., Inc.

Nicole Smith
Manager, Regulatory Promotion Group
Amgen

Session 3B

Global Promotion Review Process and Standards

Session Chair:

Lyn Hopkinson, BPharm
Vice President, Commercial Regulatory Affairs
Global Regulatory Affairs
Vertex Pharmaceuticals Incorporated

As companies expand internationally and introduce their products into more markets, the need for consistency and alignment of marketing messages across regions becomes paramount. As a result, global pharmaceutical companies are realizing the importance of establishing a clear and efficient process for the review of global materials by a multidisciplinary Global Promotional Review Committee prior to their distribution to local countries or Affiliates. Equally important to the process, and to ensuring that the review is a collaborative and constructive one, is the development of promotional review standards that can be applied to all materials.

Global Promotion Review Process

Kristen Heinlein, PharmD
US Advertising and Promotion Therapeutic Head and Group Lead
Shire

International Regulations and Global Standards

Sue Duvall, MBA, MPS, RN
GoProMo LLC

Global Process and System Effectiveness

Joanne Curley, RPh
Head of Global Promotional Regulatory Affairs and Labeling
Jazz Pharmaceuticals

Session 3C

Mock Review: A Regulatory Perspective

Session Chair:

Kristina Vlaovic, MPH
Vice President, Regulatory, Safety and Pharmacovigilance
HALOZYME Inc.

Join us as we walk through the review of a typical marketing and sales tool. We'll be discussing the merits and potential pitfalls, emphasizing important questions that should be considered, and enabling an interactive session tapping into the expertise of the moderators and audience. This session is intended for professionals who have less than three years of experience, but all are welcome. A few topics to be discussed are efficacy analyses, safety presentations, and disease education.

Facilitators:

Laura Cooper
Senior Director, Regulatory Affairs Marketed Products, Oncology
Sanofi US

Leah Palmer, PharmD
Executive Director, Regulatory Promotion
Amgen Inc.

3:00–3:30PM Refreshment Break, Exhibits, and Networking

Thanking our Media Partner: PharmaVOICE

3:30–5:00PM **Session 4: Breakout Sessions**

Session 4A

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Session 4B

Global Promotion Review Process and Standards

Session Chair:

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Head of Global Promotional Regulatory Affairs and Labeling
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Session Chair:

Kristina Vlaovic, MPH
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Sanofi US

Leah Palmer, PharmD
Executive Director, Regulatory Promotion
Amgen Inc.

5:00–6:00PM **NEW Poster Session and Networking Reception**

Poster Presentations

Board #1
Evolution of the FDA Enforcement Letter: Content and Format

Kendall Elayne Dunlap
PharmD Candidate, 2016
University of Illinois

Presenting on behalf of Ms. Dunlap:

Robert Wittenberg, PharmD
Baxter International Inc.

Maninee Patel, PharmD
Baxter International Inc.

Board #2
Submitting ECTD Promotional Labeling and Advertising Submissions With Lean Staffing

Karen D. Stith
Professional Regulatory Writer
CSC

Board #3
Global Prescription Drug Advertising and Promotion Regulations

Upasana Marwah, PharmD
Post-Doctoral Fellow
Rutgers, The State University of New Jersey

Board #4
Pharmacists in Industry: Analysis of Marketing Candidates

Alka Bhatt, PharmD
Pharmaceutical Industry Fellowship
Rutgers, The State University of New Jersey

Board #5
OPDP Enforcement Actions: January 2013-December 2015

John William Riehl, PharmD
Regulatory Advertising and Promotion Fellow
Johnson & Johnson

FRIDAY, MARCH 4

7:00AM–4:00PM Registration

7:00–8:00AM Continental Breakfast, Exhibits, and Networking

8:00–8:05AM **Welcome to Day Two**

8:05–9:35AM **Session 5: FDA Update: Recent Enforcement Actions and Guidances**

Session Chair:

Wayne L. Pines
President
Regulatory Services and Healthcare
APCO Worldwide Inc

Are you aware of all of the current issues, laws, and new guidances regarding the promotion of prescription drugs, biologics, and medical devices? FDA panelists will review the latest on policy development, enforcement, and the FDA's future initiatives, as well as the new guidances that describe the FDA's current thinking on important issues that have been raised by industry and the FDA's recommendations in these areas.

CDER Update

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

And

CDR Roberta Szydlo, RPh, MBA, RAC
Senior Regulatory Review Officer
Office of Prescription Drug Promotion
CDER, FDA

CBER Update

CDR Sonny Saini, PharmD, MBA
Senior Regulatory Operations Officer
Advertising and Promotional Labeling Branch
CBER, FDA

CDRH Update

Deborah Wolf, JD
Regulatory Counsel
Office of Compliance
CDRH, FDA

CVM Update

Thomas J. Moskal, DVM, Dipl. ACLAM, MLIS
Veterinary Medical Officer
CVM, FDA

9:35–10:00AM Refreshment Break, Exhibits, and Networking

10:00–11:30AM **Session 6: Using New and Emerging Technologies Compliantly**

Session Chair:

Dale Cooke
Owner
PhillyCooke Consulting

Consumer and health care professionals are adopting new technology platforms, especially mobile and social, as their preferred means of accessing information, yet pharmaceutical manufacturers have found it difficult to ensure their messaging meets FDA regulations in these platforms. Explore the experience of some of the industry's leading companies in overcoming these challenges while ensuring compliance with FDA regulatory requirements.

Panelists:

Matthew Boyd, MBA
Vice President Head of Regulatory North America
Sobi Inc.

Laura Kolodjeski
Director, Digital Strategy and Operations
Sanofi

Brook Yohannes, PharmD
Manager, Promotional Regulatory Affairs
Shire

Yemisi Oluwatosin, PhD
Director of Regulatory Affairs Promotional Review
AstraZeneca Pharmaceuticals

11:30AM–1:00PM Luncheon and Exhibits

Round Table Discussions

Join Round Table Discussions approximately 30 minutes into the extended luncheon. Leaders within the Marketing and Pharmaceuticals community will facilitate discussions to examine key outcomes from sessions. You are encouraged to participate and share your own experiences. To join a discussion, select one of the numbered tables.

1:00–2:10PM **Session 7: Breakout Sessions**

Session 7A

Scientific Exchange and the Responsible Sharing of Truthful and Non-Misleading Information About Medicines with HCPs

Session Chair:

Glenn Byrd, MBA, RAC
Senior Director, Specialty Care
Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals

Scientific exchange is a broadly defined concept that continues to be hotly debated and widely interpreted within the pharmaceutical industry and in the courts. In recent years, activity in this area has intensified with important court decisions and increased pressure on the FDA to clarify its position on the scope of activities and communications that fall within the scope of scientific exchange. This panel will examine and lead an interactive audience discussion on potential guiding principles on this topic.

Panelists:

Scott Moren, PharmD, MBA
Director, Medical Alignment
AstraZeneca Pharmaceuticals

Denise Williams, MD
Hematologist/Oncologist
Independent Consultant, Oncology Medical Affairs and Clinical Development

Session 7B

Advocacy Groups: When and How Should They Be Engaged?

Session Chair:

James E. Valentine, JD
Associate
Associate Hyman, Phelps & McNamara, PC

There is an open question amongst the drug development industry about how and when to best interact with patient groups regarding clinical trials. This knowledge gap has the potential to delay the start of meaningful clinical trials or lead to the conduct of less efficient trials by not tapping into the patient resource. Complex legal, ethical and regulatory issues, and ill-defined expectations can lead to unproductive relationships and disparate or unanticipated outcomes. While key stakeholders have moved to create a more effective model for engagement between research sponsors, investigators and patient groups, leading to better clinical trials, guidelines for best practices have not been shared across the industry. This session will explore opportunities for drug developers to engage with patient advocacy groups, provide an overview of the regulatory framework through which such engagement should be moderated, and explore case studies that highlight best practices for industry interactions and partnerships with these groups.

Presenters:

James E. Valentine, JD
Associate
Associate Hyman, Phelps & McNamara, PC

Rebecca Prince
Senior Corporate Counsel
Bristol-Myers Squibb

Session 7C

Review Standards for Ad Boards and Consultant Meetings

Session Chair:

Mark Gaydos
Vice President and Head
US Specialty Care 2
Head
US Advertising and Promotion Center of Excellence
North America and Global Regulatory Affairs
Sanofi

Advisory boards and consulting arrangements are common business practices that permit companies to obtain expert advice on matters ranging from clinical development plans, product positioning and promotional messaging, as well as postmarketing studies and other life cycle management activities. While representing standard business practice, such relationships with external health care professionals are fraught with risks that must be acknowledged and accounted for in order to protect companies and individuals from external allegations of illegality. We will explore the legal and regulatory risk areas associated with ad boards and consulting arrangements, from both internal and external perspectives, and discuss steps companies can take to ensure their validity and minimize associated risks.

Advisor and Consultant Arrangements: Avoiding Regulatory Peril

Mark Gaydos
Vice President and Head
US Specialty Care 2
Head
US Advertising and Promotion Center of Excellence
North America and Global Regulatory Affairs
Sanofi

Meeting Legal and Regulatory Requirements While Meeting with Your Consultants: Learning from Enforcement Trends

Linda Pissott Reig, JD
Shareholder
Buchanan, Ingersoll & Rooney PC

Legal Considerations for Advisory Boards

Felecia Ettenberg, JD
Executive Director, Promotion Integrity
Bristol-Myers Squibb

2:10–2:30PM Refreshment Break, Exhibits, and Networking

2:30–3:30PM

Session 8: Compliance Update Panel

Session Chair:

Scott Liebman
Partner
Loeb & Loeb, LLP

From drug pricing to First Amendment questions and completion of Corporate Integrity Agreements, companies are facing new and challenging compliance issues. This panel will explore these new trends and offer insight on how to navigate the uncertainty.

Panelists:

Joe Zimmerman
Former Senior Vice President, Chief Compliance Officer
Actavis & Forest

Emily Wright, JD
Senior Counsel
Pfizer

Howard Dorfman, JD
Founder
H. L. Dorfman Pharmaceutical Consulting

3:30–4:00PM

Closing Session: Question and Answer with FDA

Session Chair:

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Use this unique opportunity to bring your pressing questions for the FDA to address in person. This session will attempt to answer any remaining questions from earlier sessions and allow you to ask new questions to our FDA speakers.

Panelists:

Thomas W. Abrams, MBA, RPh
Director
Office of Prescription Drug Promotion
CDER, FDA

CDR Roberta Szydlo, RPh, MBA, RAC
Senior Regulatory Review Officer
Office of Prescription Drug Promotion
CDER, FDA

Sonny Saini, PharmD
Regulatory Health Project Manager
Advertising and Promotional Labeling Branch
CBER, FDA

Alpita Popat, MBA, PharmD
Consumer Safety Officer, Advertising, Promotional and Labeling Branch
CBER, FDA

Deborah Wolf, JD
Regulatory Counsel
Office of Compliance
CDRH

Thomas J. Moskal, DVM, Dipl. ACLAM, MLIS
Veterinary Medical Officer
CVM, FDA

Exhibiting Companies

As of February 25, 2016

- DIA
- ENLASO
- Framework Solutions, Inc.
- Genentech, A Member of the Roche Group
- Gilead Sciences
- Opus Regulatory
- Porzio Life Sciences, LLC
- Veeva Systems, Inc.

About DIA

Develop. Innovate. Advance.

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.

DIA 2016

JUNE 26–30 | PHILADELPHIA, PA

DIA 2016 is packed with 175+ educational offerings over 22 tracks on today's hottest topics. It is our largest interdisciplinary event, bringing together a global network of 7,000+ life sciences professionals from industry, academia, regulatory and government agencies, and patient and philanthropic organizations from around the globe, to foster innovation in the discovery, development, and life cycle management of health care products.

Just Announced – DIA 2016 Co-Chairs:

Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency

Gigi Hirsch, MD
Executive Director, MIT Center for Biomedical Innovation

Featured Sessions:

- Disease Interception: Shifting the Paradigm from Treatment to Prevention of Disease
- Expedited Reviews and Other Pathways to Speed up Access to Medicines
- Lessons Learned from Eight Years of Drug Development Tool/Novel Methodology Qualification
- Regulatory Science Considerations Applying to Novel Biologics and Bifunctional Biologics Development
- Infectious Disease Containment and Lessons Learned

Featured Highlights

- Global regulatory presence with representatives from FDA, EMA, PMDA, Health Canada, and more
- NEW Engage and Exchange Sessions: Engage with fellow attendees in a new, collaborative learning environment
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