DIA

Advertising and Promotion Regulatory Affairs Conference

March 7: Primer Course | March 8-9: Conference
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM COMMITTEE

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

Micheline Awad, MBA
Director Regulatory Affairs, Advertising and Promotion
Neurocrine Biosciences, Inc.

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

Dale Cooke, MA
President
PhillyCooke Consulting

Mark Gaydos
Vice President, NA General Medicines/US Advertising and Promotion, Global Regulatory Affairs
Sanofi

Mary L Raber Johnson, PhD, RAC
Assistant Professor, Clinical
The Ohio State University, College of Pharmacy

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

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

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Overview

DIA's *Advertising and Promotions Regulatory Affairs Conference* offers a comprehensive agenda covering the latest updates in the ad promo regulatory space. Industry experts will share best practices for ad promo launch strategy, discuss global ad promo review considerations, and evaluate how clinical trial design impacts promotional practice. Hear from FDA on the latest OPDP draft guidance and initiatives, enforcement actions, social science research and electronic Common Technical Document (eCTD) submission process.

Highlights

- Ad Promo Primer Course prior to the start of the conference for new-to-the-field professionals in the Ad Promo space
- Two breakout tracks to accommodate both novice and senior professionals
- Creative and interactive sessions with speakers from FDA and industry experts
- Exhibit Hall with numerous vendors displaying new solutions and services

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

Schedule At-A-Glance

Track A: Senior Level **Track B:** Beginner Level

PRIMER COURSE | WEDNESDAY, MARCH 7		ROOM
12:30PM-5:00PM	Primer Registration	Foyer A-C
1:30-5:00PM	**Ad Promo Primer**	Forest Glen
DAY ONE | THURSDAY, MARCH 8		**ROOM**
7:15AM-5:30PM	Registration	Foyer A-C
7:15-8:15AM	Continental Breakfast in the Exhibit Hall	Salon A-C
8:15-8:30AM	**Welcome and Opening Remarks**	Salon D
8:30-9:00AM	**Session 1:** Keynote Address	Salon D
9:00-10:00AM	**Session 2:** FDA Draft Guidance and Initiatives	Salon D
10:00-10:30AM	Refreshments, Exhibits, and Networking Break	Salon A-C
10:30-11:45AM	**Session 3:** Industry Promotional Review Committee Best Practices	Salon D
11:45AM-1:00PM	Luncheon, Exhibits, and Networking	Salon A-C
1:00-2:00PM	**Session 4:** Breakout Sessions **Track A:** Addressing the Multi-Screen World: Promotional Challenges of New and Emerging Technologies **Track B:** Global Promotional Review Process and Considerations	 Salon D White Flint Amphitheater
2:00-3:00PM	**Session 5:** Breakout Sessions **Track A:** Communicating Product Risk in Today's Evolving Regulatory Landscape **Track B:** Building an Effective and Compliant Product Communication Strategy for Payers, Formulary Committees, and Similar Entities	 Salon D White Flint Amphitheater
3:00-3:30PM	Refreshments, Exhibits, and Networking Break	Salon A-C
3:30-4:30PM	**Session 6:** Legal Update	Salon D
4:30-5:30PM	**Session 7:** OPDP Research Panel	Salon D
5:30-6:30PM	Reception and Exhibits	Salon A-C
DAY TWO | FRIDAY, MARCH 9		**ROOM**
7:15AM-3:00PM	Registration	Foyer A-C
7:15-8:15AM	Continental Breakfast in the Exhibit Hall	Salon A-C
8:15-8:45AM	**Session 8:** DIA Community Presentation	Salon D
8:45-9:45AM	**Session 9:** FDA: Focus on Enforcement	Salon D
9:45-10:15AM	Refreshments, Exhibits, and Networking Break	Salon A-C
10:15-11:45AM	**Session 10:** Breakout Sessions **Track A:** Best Practices for Ad Promo Launch Strategy **Track B:** Innovations in Clinical Trial Design Impacting Promotional Practices	 Salon D White Flint Amphitheater
11:45AM-12:45PM	Luncheon, Exhibits, and Networking	Salon A-C
12:45-1:45PM	**Session 11:** Breakout Sessions **Track A:** Case Study: A Health Literacy Approach to Improve the Understandability and Usability of Consumer Brief Summaries **Track B:** Building Bridges: Creating and Maintaining a Productive Relationship with FDA on Advertising and Promotion Issues	 Salon D White Flint Amphitheater
1:45-2:45PM	**Session 12:** FDA's Guidance on Electronic Submissions of Promotional Materials	Salon D
2:45-3:00PM	**Wrap-Up**	Salon D

Learning objectives

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

- Identify the trends reflected in the latest enforcement actions and policies issued by the FDA and other legal and regulatory authorities
- Discuss gaps in regulatory policy
- 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 emerging promotional and non-promotional tactics trending in the pharmaceutical industry that require creative and thoughtful regulatory review
- Analyze effective digital and social media strategies designed to meet the challenges of ensuring compliance with FDA regulatory requirements

Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 14.50 contact hours or 1.450 continuing education units (CEUs). Participants must attend the entire conference or primer in order to be able to receive ACPE credit. **No partial credit will be awarded**.

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, APRIL 20, 2018

Type of Activity: Knowledge

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. If ACPE credit is not requested by **Friday, April 20, 2018**, the CEU request will not be transmitted through to the CPE Monitor. 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. Obtain your NABP e-Profile at nabp.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 the up to 1.4 CEUs. Participants must attend the entire conference or primer 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 (primer, if applicable), turn in the attendance verification form, 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 23, 2018**.

Continuing Education Credit Allocation

Ad Promo Primer: Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-015-L04-P; IACET .3 CEUs

Advertising and Promotion Regulatory Affairs Conference: Pharmacy 11.25 contact hours or 1.125 CEUS; UAN: 0286-0000-18-016-L04-P; IACET 1.1 CEUs

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 course

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- Select 'Sign in' at the top right
- Enter your User ID and Password
- Go to 'My Account'
- View 'My Presentation'

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

PRIMER | WEDNESDAY, MARCH 7

12:30PM-5:00PM

Primer Registration

1:30-5:00PM

Ad Promo Primer

Instructors

Dwight Bowen, Jr., PharmD, RPh
Senior Lead (Director), US Advertising and Promotion Regulatory Affairs
Shire

Jess Amchin, MD, JD
President
Jess Amchin Consulting, LLC

If you are new, or relatively new, to the preparation or review of advertising and/or promotional materials, this primer is for you! This course 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.

At the conclusion of this primer, 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

DAY ONE | THURSDAY, MARCH 8

7:15AM-5:30PM

Registration

7:15-8:15AM

Continental Breakfast in the Exhibit Hall

8:15-8:30AM

Welcome and Opening Remarks

Session Co-Chairs

Sudip S. Parikh, PhD
Senior Vice President and Managing Director, DIA Americas
DIA

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

8:30-9:00AM

Session 1

Keynote Address

Session Chair
Wayne Pines
President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

Keynote Speaker
Rebecca K. Wood
Chief Counsel
FDA

9:00-10:00AM

Session 2

FDA Draft Guidance and Initiatives

Session Chair
Wayne Pines
President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

Hear directly from FDA's Office of Prescription Promotion on the latest guidances related to medical product communications. The agency will share its thinking on communication of healthcare economic information (HCEI) to payers, as well as information for firms about how FDA evaluates firms' medical product communications that present information that is not contained in the FDA-required labeling for the product, but that may be consistent with the FDA-required labeling for the product. The agency will also discuss the final guidance on product name placement in promotional labeling and advertisements for prescription drugs.

Panelists

Catherine B. Gray, PharmD
Staff Supervisor, Office of Prescription Drug Promotion, OMP
CDER, FDA

Sheila Ryan, PharmD, MPH, RAC
Policy Team Leader, OPDP
FDA

Elizabeth Pepinsky
Health Science Policy Analyst, OPDP
FDA

Kemi Asante, PharmD, MPH, RAC
Health Science Policy Analyst, OPDP
FDA

10:00-10:30AM

Refreshments, Exhibits, and Networking Break

DAY ONE | THURSDAY, MARCH 8

10:30-11:45AM

Session 3

Industry Promotional Review Committee Best Practices

Session Co-Chairs

Kimberly Belsky, MS
Senior Director, Regulatory Affairs,
Regulatory Policy and Intelligence
Mallinckrodt Pharmaceuticals

Dolores Shank-Samiec, MS
Executive Director, Office of Promotion and Advertising Review
Merck

This interactive session will provide you with insights on review committee best practices to create an efficient and high-functioning team, as well as an understanding of challenges resulting from today's regulatory and technology environment. This session will also tips to overcome them.

Panelists

Kimberly Belsky, MS
Senior Director, Regulatory Affairs,
Regulatory Policy and Intelligence
Mallinckrodt Pharmaceuticals

Dolores Shank-Samiec, MS
Executive Director, Office of Promotion and Advertising Review
Merck

11:45AM-1:00PM

Luncheon, Exhibits, and Networking

1:00-2:00PM

Session 4

Breakout Sessions

TRACK A

Addressing the Multi-Screen World: Promotional Challenges of New and Emerging Technologies

Session Chair

Dale Cooke, MA
President
PhillyCooke Consulting

Patients, caregivers, and HCPs are dividing their attention among all of their devices; and that means reaching the right audience means providing messaging anywhere and anytime people want it. This has proved challenging for pharmaceutical companies. This session will address some of the more recent developments in multi-screen messaging and provide you with the information you need to ensure compliance of your communications, including the issues of advertising/promotional challenges inside mobile apps, multi-device tracking and privacy concerns, and point of care promotional communications and their integration into a broader campaign.

Panelists

Kristi L. Wolff
Partner
Kelley Drye & Warren LLP

Geoffrey McCleary
Executive, Mobile and Connected Health, Director, Digital Health
PricewaterhouseCoopers

Julie Cain
Vice President, Product Strategy
PatientPoint

TRACK B

Global Promotional Review Process and Considerations

Session Chair

Sue Duvall, RN, MPA
Head North America Advertising and Promotion, Regulatory Affairs
Mylan

There is an increasing need for consistency and alignment of marketing messages across regions as companies expand internationally and introduce their products into more markets. Global pharmaceutical companies are realizing the importance of establishing a clear and efficient process for the review of global messaging and draft materials by a multidisciplinary Global Promotional Review Committee prior to their distribution to local countries or Affiliates. The first part of this session will provide considerations and best practices for the global promotional review process. The second part will provide insights into how to navigate Canada's drug advertising process.

John K. Wong, MPharm
Executive Director, Regulatory Drug Advertising, and Promotion
TPI Reg, Canada

Lisa Schatz, PharmD, MBA
Director, International Regulatory Affairs Advertising and Promotion
Abbvie, Inc.

Thank you to our media partners:

PM360 THE ESSENTIAL RESOURCE FOR PHARMA MARKETERS

PharmaVOICE

DAY ONE | THURSDAY, MARCH 8

2:00-3:00PM

Session 5
Breakout Sessions

TRACK A
Communicating Product Risk in Today's Evolving Regulatory Landscape

Session Chair
Christine Novak, PharmD
Associate Director, Commercial Regulatory Affairs
Bristol-Myers Squibb

Pharmaceutical companies are constantly evaluating the appropriate balance and presentation of risk and benefit information within promotional material. This has proved to be a constant challenge for pharmaceutical companies in regards to certain types of promotional material. This session will discuss some of the recent developments regarding how a product's risk information could be communicated - with a focus on the presentation of risk information in materials directed towards consumers.

Christine Novak, PharmD
Associate Director, Commercial Regulatory Affairs
Bristol-Myers Squibb

Dwight Bowen, Jr., PharmD, RPh
Senior Lead (Director), US Advertising and Promotion Regulatory Affairs
Shire

John Kamp
Executive Director
Coalition For Healthcare Communication

TRACK B
Building an Effective and Compliant Product Communication Strategy for Payers, Formulary Committees, and Similar Entities

Session Chair
Sheetal Patel, PharmD
Head, Regulatory Advertising and Promotion
Johnson & Johnson International

With the advent of real world evidence and other continued evidence generation strategies of a product, building an effective and compliant product communication strategy is valuable to help payers, formulary committees, and other similar entities determine budgets and needs of their covered lives. This session will outline the current regulatory framework that allows the opportunity to communicate product information compliantly, explore the ability to effectively operationalize these efforts within an organization, and discuss future impact through regulatory reform of product communication to payers, formulary committees, and similar entities.

Operationalizing an Effective and Compliant Product Communication Strategy
Amy C. Van Sant, PharmD, MBA
President, Medical Affairs
Ashfield Healthcare

Legal Framework and Regulatory Outlook
Katlin McKelvie Backfield, JD
Attorney/Consultant
Backfield PLLC

3:00-3:30PM

Refreshments, Exhibits, and Networking Break

3:30-4:30PM

Session 6
Legal Update

Session Chair
Coleen Klasmeier, JD
Partner and Global Coordinator, FDMD Regulatory Practice
Sidley Austin, LLP

Advertising and promotion issues continue to arise in a wide range of legal contexts, from civil litigation brought by injured plaintiffs to state and local authorities acting under general consumer protection statutes and nuisance principles and a variety of civil and criminal investigations and settlement agreements arising under the False Claims Act. At the same time, the Food and Drug Administration's implementation of the advertising and promotion provisions of the Federal Food, Drug, and Cosmetic Act has continued to develop in response to First Amendment pressures and other shifts in the external environment. This session will identify and summarize key developments in the law affecting manufacturer communications, with a focus on characterizing the enforcement and litigation risks confronting regulated entities. Our focus will include practical risk mitigation techniques and effective tools to remain up-to-date as the legal landscape continues to shift in this important area of manufacturer activity.

Key Developments and FDA Implications
Coleen Klasmeier, JD
Partner and Global Coordinator, FDMD Regulatory Practice
Sidley Austin, LLP

Civil Litigation Developments
Michael J. Hulka
Senior Director, Assistant General Counsel
Eli Lilly and Company

Criminal Enforcement and State AG Activity
Margaret Sparks
Associate Vice President
Sanofi US

DAY ONE | THURSDAY, MARCH 8

4:30-5:30PM

Session 7
OPDP Research Panel

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

Individual FDA/OPDP researchers will present topics of their own research and will highlight plans for upcoming research. Gain a better understanding of the FDA/OPDP Research program and how it may contribute to knowledge, guidance, and policy development.

Research Update and Preview from OPDP
Kathryn Aikin, PhD
Senior Social Science Analyst, Research Team Lead, OPDP
CDER, FDA

Who's Watching and How is it Structured: The Major Statement in DTC Television Ads
Amie O'Donoghue, PhD
Social Science Analyst, OPDP
CDER, FDA

A Content Analysis of the Major Statement in DTC Television Ads
Helen Sullivan, PhD, MPH
Social Science Analyst, OPDP
CDER, FDA

5:30-6:30PM

Reception and Exhibits

DAY TWO | FRIDAY, MARCH 9

7:15AM-3:00PM

Registration

7:15-8:15AM

Continental Breakfast in the Exhibit Hall

8:15-8:45AM

Session 8
DIA Community Presentation

Session Co-Chairs
Kimberly Belsky, MS
Senior Director, Regulatory Affairs, Regulatory Policy and Intelligence
Mallinckrodt Pharmaceuticals

Dolores Shank-Samiec, MS
Executive Director, Office of Promotion and Advertising Review
Merck

Learn and engage! Presented by DIA's Advertising and Promotion Working Group, this session will provide an overview of topics recently discussed, key takeaways, and how you can enhance your knowledge throughout the year by becoming involved in the Advertising and Promotion Working Group.

8:45-9:45AM

Session 9
FDA: Focus on Enforcement

Session Chair
Wayne Pines
President, Regulatory Services and Healthcare
APCO Worldwide, Inc.

This session will focus on FDA's recent enforcement actions. Representatives from four FDA medical centers will dive deeply into specific recent enforcement actions, which will offer insights into the agency's thought process on enforcement actions.

Thomas J. Moskal, DVM
Veterinary Medical Officer, CVM
FDA

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

Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, OCBQ
CBER, FDA

Thomas Abrams, MBA
Director, Office of Prescription Drug Promotion, OMP
CDER, FDA

9:45-10:15AM

Refreshments, Exhibits, and Networking Break

DAY TWO | FRIDAY, MARCH 9

10:15-11:45AM

Session 10
Breakout Sessions

TRACK A
Best Practices for Ad Promo Launch Strategy

Session Chair
Micheline Awad, MBA
Director, Regulatory Affairs, Advertising and Promotion
Neurocrine Biosciences, Inc.

This session will focus on providing insights and best practices as well as tips on overcoming challenges, managing launch teams, and developing senior management support for a successful product launch for small companies preparing to launch their first product or experienced companies looking to improve their launch strategies.

Launch Success – Planning, Planning, Planning!
Rob Quinn
Director Promotional Regulatory Affairs- Oncology
AstraZeneca

Launch Execution – Team Dynamics
Eileen Valenta, MBA
President
Valenta Consulting

Planning for Success
Blythe Buchanan
Director, Regulatory Sciences Advertising and Promotion
Biogen

TRACK B
Innovations in Clinical Trial Design Impacting Promotional Practices

Session Chair
Mary L. Raber Johnson, PhD, RAC
Assistant Professor, Clinical
The Ohio State University College of Pharmacy

Clinical trial designs intended to support product approvals have evolved due to many factors including consideration of the patient perspective. The 21st Century Cures Act described patient-centered initiatives and modified standards of evidence that will likely be part of future approval and promotional landscapes. As illustrated with recent approvals in gene therapy and basket-trial design, there are unique considerations for the patient experience, providing opportunities to evolve promotional practices. This session is a multidisciplinary perspective on the impact of dynamics such as these on product promotion.

Progress Toward a More Patient-focused Approach to Drug Development and Regulatory Review
Eugene Sullivan, MD
Principal
EJS Consulting, LLC

A Case-Based Review: Does Clinical Trial Design Drive Promotional Strategy or is it the Other Way Around?
Wolf Gallwitz, PhD, MBA
Chief Scientific Officer
Razorfish Health

How Technology is Enabling Patient-Centric Drug Development and Promotion
Brandon Ashcraft
Senior Vice President, Digital Solutions
Razorfish Health

Panelist
Joining the speakers
Alexander Bragg
Strategy and Planning Advertising Executive
Fingerpaint Marketing

11:45AM-12:45PM

Luncheon, Exhibits, and Networking

DAY TWO | FRIDAY, MARCH 9

12:45-1:45PM

Session 11
Breakout Sessions

TRACK A

Case Study: A Health Literacy Approach to Improve the Understandability and Usability of Consumer Brief Summaries

Session Chair
Michele Sharp, PharmD
Senior Director, Global Regulatory Affairs
Eli Lilly and Company

Print pharmaceutical advertisements in the US require inclusion of a brief summary of side effects, warnings, and contraindications from the labeling. The full prescribing information, which sponsors have traditionally used to fulfill the brief summary requirement, does not adhere to health literacy best practices, limiting its value to consumers. Studies increasingly show that health information that adheres to health literacy best practices, and is tested with users, improves people's comprehension and health behaviors. This session will focus on recent research to improve the understandability and usability of brief summaries with consumers.

Lori Hall, BSN
Director – Health Literacy
Eli Lilly and Company

Linda Neuhauser, DrPH, MPH
Clinical Professor, Community Health and Human Development;
Principal Investigator, Health Research for Action Center
University of California – Berkeley, School of Public Health

TRACK B

Building Bridges: Creating and Maintaining a Productive Relationship with FDA on Advertising and Promotion Issues

Session Chair
Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

For US regulatory affairs professionals, the FDA is a key customer and establishing an effective, productive relationship with the agency cannot be left to chance. A solid foundation for this relationship is a keen understanding of the role and objectives of the FDA on advertising and promotion issues. With that knowledge, company regulatory professionals can begin to build and then sustain a strategic, mutually respectful relationship with FDA that can result in greater efficiency and transparency, more effective promotional materials, and fewer surprises.

Panelists
Jean-Ah Kang, PharmD
Special Assistant to the Director, Office of Prescription Drug Promotion
CDER, FDA

Leah Palmer, PharmD
Consultant, Regulatory Promotion

Sheetal Patel, PharmD
Head, Regulatory Advertising and Promotion
Johnson & Johnson International

Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, OCBQ
CBER, FDA

1:45-2:45PM

Session 12
FDA's Guidance on Electronic Submissions of Promotional Materials

Session Chair
Jason Cober
Lead Project Manager, OPDP
FDA

Join members of FDA's Office of Prescription Drug Promotion (OPDP) and an industry representative as they provide in-depth insight and advice regarding the submission of promotional materials in electronic Common Technical Document (eCTD) format to OPDP. FDA will provide a brief overview of the Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs draft guidance, review selected portions of the guidance in detail, and provide helpful technical tips for successfully submitting promotional materials to FDA as described in the guidance. An example of how one firm transitioned to eCTD will be shared. The presentation will wrap-up with a brief Q&A session.

Panelists

Jason Cober
Lead Project Manager, OPDP
FDA

Josephine Secnik, MS, MBA
Director – Ad/Promo Regulatory Affairs
Eli Lilly and Company

Kemi Asante, PharmD, MPH, RAC
Health Science Policy Analyst, OPDP
FDA

2:45-3:00PM

Wrap-Up

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

3:00PM

Conference Adjourns