Advertising and Promotion Regulatory Affairs Conference

Primer: February 22 | Conference: February 23-24
Omni Shoreham Hotel | Washington, DC

PROGRAM COMMITTEE

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

Dale Cooke
Owner
PhillyCooke Consulting

Mark Gaydos
Vice President, North America General Medicines and Established Products, US Advertising and Promotion, Global Regulatory Affairs
Sanofi US

Tracy Rockney, JD
Co-Founder and Managing Partner
OneSource Regulatory

Paul Savidge, JD, MBA
Senior Regulatory Counsel
Spark Therapeutics, Inc.

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

PROGRAM ADVISORS

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

Lucy Rose
President
Lucy Rose and Associates, LLC

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

Overview

DIA's *Advertising and Promotions Regulatory Affairs Conference* (formerly known as the DIA Marketing Pharmaceutical Conference) has a comprehensive agenda covering the latest updates in the ad promo regulatory space. Participate in discussions on the new and emerging industry trends as well as examine and analyze new FDA guidances and initiatives.

This conference will provide you with the opportunity to network with regulatory and legal professionals, as well as industry leaders in advertising and promotion. Whether you're just starting out or have years of experience and knowledge, this conference can be customized to meet your needs!

Highlights

- **DIA's AdPromo Benchmarking Survey Results.** Members from DIA's Regulatory Affairs Ad Promo Community will present the results on industry best practices and trends during the breakfast presentation.
- **New Tracks!** This year the program is broken out into senior and beginner session tracks to allow you to get the information you need most.
- **Round Table Discussion Luncheon.** Share your conference thoughts and takeaways during Friday's luncheon led by designated community leader.
- **Interactive Sessions.** Learn from industry experts and gain the latest information from FDA panelists.

Who Should Attend

Professionals involved in:

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

This Conference has been approved by the Regulatory Affairs Professionals Society for 12 RAC credits.

Schedule At-A-Glance

Track A: Senior Session **Track B:** Beginner Session

PRIMER | WEDNESDAY, FEBRUARY 22		
12:00-5:00PM	Primer Registration	Governor's Room Foyer
1:30-5:00PM	**Ad Promo Primer**	Governor's Room
DAY ONE | THURSDAY, FEBRUARY 23		
7:30AM-6:00PM	Registration	Blue Room Prefunction
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking	Blue Room Prefunction
8:30-8:45AM	**Welcome and Opening Remarks**	Blue Room
8:45-9:45AM	**Session 1:** FDA Focus on Enforcement	Blue Room
9:45-11:00AM	**Session 2:** FDA Draft Guidance and Initiatives	Blue Room
11:00–11:30AM	Refreshment Break, Exhibits, and Networking	Blue Room Prefunction
11:30AM–1:00PM	**Session 3:** OPDP Research Agenda	Blue Room
1:00–2:00PM	**Networking Luncheon**	Empire Ballroom
2:00-3:30PM	**Session 4:** Breakout Sessions **Track A:** Considerations for Expanding Proactive Communications by Biopharmaceutical Manufacturers to Population Health Decision-Makers **Track B:** Deep Dive: Live and Field-Based Tactics	Blue Room Hampton Ballroom
3:30-4:00PM	Refreshment Break, Exhibits, and Networking	Blue Room Prefunction
4:00–5:30PM	**Session 5:** Navigating the Murky Waters of Off-Label Communications: Promotion, Commercial Speech, and Scientific Exchange	Blue Room
5:30–6:00PM	**Session 6:** FDA Q&A	Blue Room
6:00-7:00PM	**Poster Session and Networking Reception**	Blue Room Prefunction
DAY TWO | FRIDAY, FEBRUARY 24		
7:00AM-4:00PM	Registration	Blue Room Prefunction
7:00-8:00AM	Continental Breakfast, Exhibits, and Networking	Blue Room Prefunction
7:15-8:00AM	**DIA Regulatory Affairs Advertising and Promotion Working Group Benchmarking Survey**	Blue Room
8:00-8:05AM	**Welcome to Day Two**	Blue Room
8:05–8:35AM	**Takeaways from Day One and Q&A**	Blue Room
8:35-9:35AM	**Session 7:** Mobile Apps – When Are They Promotions, When Are They Regulated Devices?	Blue Room
9:35-10:00AM	Refreshments, Exhibits, and Networking Break	Blue Room Prefunction
10:00-11:30AM	**Session 8:** Breakout Sessions **Track A:** Ad-Promo's Role in the Adoption of Technology across the Organization **Track B:** Deep Dive: Digital Tactics	Blue Room Hampton Ballroom
11:30AM-1:00PM	Round Table Discussion Luncheon	Empire Ballroom
1:00-2:10PM	**Session 9:** Breakout Sessions **Track A:** Considerations for Developing a Productive Advertising and Promotion Team **Track B:** Building Bridges: Creating and Maintaining a Productive Relationship with FDA on Advertising and Promotion Issues	Blue Room Hampton Ballroom
2:10-2:30PM	Refreshments and Networking Break	Blue Room Prefunction
2:30-3:30PM	**Session 10:** Patient Support Programs	Blue Room
3:30-4:00PM	**Closing Session:** FDA in the Trump Administration	Blue Room

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 Credit

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for the CEUs indicated below. Type of Activity: Knowledge

ACPE Credit Requests MUST BE SUBMITTED by Saturday, April 8, 2017

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 Saturday, April 8, 2017, 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. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net

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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 1.7 CEUs. Participants must attend the entire forum in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Ad Promo Primer..... 0.3 CEUs
Conference ..... 1.3 CEUs

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit, you must attend the forum (Primer and/or Short Course(s), if applicable), sign in at the registration desk, complete the "Verification of Attendance" form located in your meeting folder, turn in your form to the registration desk at the conclusion of the forum, 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 10, 2017.**

To view DIA's Grievance Policy, visit DIAglobal.org/CE

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. Disclosures will be included in the handout materials. This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Continuing Education Allocation

Ad Promo Primer: Pharmacy: 3.25 Contact Hours or .325 CEUs, UAN: 0286-0000-17-022-L04-P; IACET .3 CEUs

Welcome and Session 1: FDA Focus on Enforcement: Pharmacy: 1.25 Contact Hours or .125 CEUs, UAN: 0286-0000-17-020-L04-P

Session 2: FDA Draft Guidance and Initiatives: Pharmacy: 1.25 Contact Hours or .125 CEUs, UAN: 0286-0000-17-021-L04-P

Session 3: OPDP Research Agenda: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-023-L04-P

Session 4A: Considerations for Expanding Proactive Communications by Biopharmaceutical Manufacturers to Population Health Decision Makers: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-024-L04-P

Session 4B: Deep Dive: Live and Field-Based Tactics: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-025-L04-P

Session 5: Navigating the Murky Waters of Off-Label Communications: Promotion, Commercial Speech and Scientific Exchange: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-026-L04-P

Session 6: Question and Answer Session with FDA: Pharmacy: .5 Contact Hours or .05 CEUs, UAN: 0286-0000-17-027-L04-P

Takeaways From Day 1: Question and Answer Session: Pharmacy: .5 Contact Hours or .05 CEUs, UAN: 0286-0000-17-028-L04-P

Session 7: Mobile Apps – When Are They Promotions, When Are They Regulated Devices?: Pharmacy: 1 Contact Hours or .1 CEUs, UAN: 0286-0000-17-029-L04-P

Session 8A: Ad-Promo's Role in the Adoption of Technology Across the Organization: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-030-L04-P

Session 8B: Deep Dive: Digital Tactics: Pharmacy: 1.5 Contact Hours or .15 CEUs, UAN: 0286-0000-17-031-L04-P

Session 9A: Considerations for Developing a Productive Advertising and Promotion Team: Pharmacy: 1.25 Contact Hours or .125 CEUs, UAN: 0286-0000-17-032-L04-P

Session 9B: Building Bridges: Creating and Maintaining a Productive Relationship with FDA on Advertising and Promotion Issues: Pharmacy: 1.25 Contact Hours or .125 CEUs, UAN: 0286-0000-17-033-L04-P

Session 10: Patient Support Programs: Pharmacy: 1 Contact Hours or .1 CEUs, UAN: 0286-0000-17-034-L04-P

Closing Session: FDA in the Trump Administration: Pharmacy: .5 Contact Hours or .05 CEUs, UAN: 0286-0000-17-035-L04-P

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12:00-5:00PM — **Primer Registration**

1:30-5:00PM

Ad Promo Primer

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

Moderator

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Instructors

Dwight Bowen, Jr., PharmD
Global Regulatory Affairs- US Advertising/Promotion
Eli Lilly and Company

Elizabeth Jobes
Legal Counsel and Head of Corporate Compliance
Spark Therapeutics

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

DAY ONE | THURSDAY, FEBRUARY 23

7:30AM-6:00PM — **Registration**

7:30-8:30AM — **Continental Breakfast, Exhibits, and Networking**

8:30-8:45AM — **Welcome and Opening Remarks**

8:45-9:45AM

Session 1
FDA: Focus on Enforcement

This session will focus on FDA's new initiatives and recent enforcement actions. Representatives from four FDA centers will dive deeper into specific recent enforcement actions, which will offer insights into the agency's thought process on enforcement actions. The Office of Prescription Drug Promotion Director, Tom Abrams, will share an update on recent policy initiatives, and how they have evolved at the agency based on the November hearing, as well as other initiatives emerging from FDA in the new year.

Session Chair

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

Speakers

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

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

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

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

9:45–11:00AM

Session 2
FDA Draft Guidance and Initiatives

Hear directly from FDA's OPDP on the two new draft guidances related to medical product communications. The agency will share their thinking on communication of health care economic information (HCEI) to payors about approved drugs, and their recommendations regarding communications to payors about investigational drugs and devices that are not yet approved or cleared for any use. FDA will also discuss the draft guidance concerning medical communications that include data and information that are not contained in a products' FDA-required labeling, but that are consistent with the approved or cleared FDA-required labeling for the products. Finally, FDA will describe rule-making efforts currently underway regarding the Patient Medication Information (PMI) Initiative led by the Office of Medical Policy Initiatives.

Session Chair

Michael A. Sauers
Advertising and Promotion Policy Staff Supervisor
CDER, OMP, OPDP, FDA

Speakers

Catherine B. Gray, PharmD
Advertising and Promotion Policy Deputy Staff Supervisor, OMP, OPDP
CDER, FDA

Elaine Cunningham
Senior Regulatory Review Officer, OPDP
CDER, FDA

Elisabeth Walther, JD, PharmD
Regulatory Counsel, Health Scientist Policy Analyst, OMP, OMPI
CDER, FDA

11:00-11:30AM — **Refreshments, Exhibits, and Networking Break**

DAY ONE | THURSDAY, FEBRUARY 23

11:30AM-1:00PM

Session 3
OPDP Research Agenda

Individual FDA 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 guidance and policy development.

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

Speakers
Kathryn Aikin, PhD
Team Lead, Social Science Analyst, OPDP
CDER, FDA

Kevin Betts, PhD
Social Science Analyst, OPDP
FDA

Amie O'Donoghue, PhD
Social Science Analyst, OPDP
CDER, FDA

Helen Sullivan, PhD, MPH
MPH Social Science Analyst, OPDP
CDER, FDA

1:00-2:00PM

Networking Luncheon

2:00–3:30PM

Session 4: Breakout Sessions

TRACK A

Considerations for Expanding Proactive Communications by Biopharmaceutical Manufacturers to Population Health Decision Makers

This session will provide a landscape of the current requirements for proactive communications of HCEI, highlighting the challenges and barriers within the existing infrastructure. This panel discussion will also provide key stakeholder perspectives on why access to HCEI is critical to better care for patients and discuss possible solutions to enable better and timelier communications between biopharmaceutical manufacturers and population health decision makers. Potential implications for patients will also be discussed. Finally, this session will discuss the implications of new draft guidance released by the FDA governing manufacturer communications with payors.

Session Chair
Soumi Saha, PharmD, JD
Assistant Director of Pharmacy and Regulatory Affairs
Academy of Managed Care Pharmacy

Panelists
Michelle Drozd, ScM
Deputy Vice President, Policy and Research
Pharmaceutical Research and Manufacturers of America

Amy Duhig, PhD
Senior Director, Outcomes Research,
Global Health Economics and Outcomes Research
Xcenda

Morgan Romine, MPA
Managing Associate
Duke-Robert J. Margolis, MD, Center for Health Policy

TRACK B

Deep Dive: Live and Field-Based Tactics

We know regulatory requirements, but how you ensure compliance varies on the field tactic. Hear experts discuss regulatory, legal, and compliance considerations for different field tactics such as Commercial Conference Booths, Field Sales calls, peer-to-peer communications, and MSL interactions.

Session Chair
Bhavana Desai, MBA
Senior Director, Advertising, Promotion and Labeling Regulator Affairs
Avanir Pharmaceuticals, Inc.

Panelists
Kelly N. Reeves, JD
Attorney
King & Spalding LLP

Wanda Hicks Hill, RPh, JD
Vice President, US Regulatory Affairs, Head, Regulatory Advertising and Promotion Policy
GlaxoSmithKline

Daniel Spicehandler, JD
Director, Risk and Accountability Compliance
Nordisk Inc.

3:30–4:00PM

Refreshments, Exhibits, and Networking Break

DAY ONE | THURSDAY, FEBRUARY 23

4:00–5:30PM

Session 5
Navigating the Murky Waters of Off-Label Communications: Promotion, Commercial Speech, and Scientific Exchange

In recent years, the already challenging issues associated with sponsors' off-label communications have become even more complicated. Following recent Court decisions favoring less government restriction of commercial speech in this area, industry and other interested parties anxiously await FDA's broader policy position, which it committed to comprehensively reviewing in the wake of these First Amendment cases. In the meantime, and also considering the perspectives presented at FDA's November 2016 public hearing, we will consider where companies might consider altering their traditional policies and where they will want to continue exercising great caution.

Session Chair

Mark Gaydos
Vice President, North America General Medicines and Established Products, US Advertising and Promotion, Global Regulatory Affairs
Sanofi US

Speakers

Michael Labson, JD
Partner
Covington & Burling LLP

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

Michael Zilligen
President, CommonHealth Payer Marketing, Healthworld Payer Marketing
Ogilvy

5:30–6:00PM

Session 6
FDA Q&A

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 question to our FDA speakers.

Session Chair

Lucy Rose, MBA
President
Lucy Rose and Associates, LLC

Panelists

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

Dorothy McAdams
Supervisor VMO
CVM, FDA

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

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

6:00–7:00PM

Poster Session and Networking Reception

Poster Presentations

Board 1
Eli Lilly's Transition to eCTD Submission for Ad/Promo Materials

Josephine Secnick, MBA, MS
Principal Advisor – Regulatory
Eli Lilly and Company

Board 2
A Comparison of Promotional Regulations Between the US Food and Drug Administration and the European

Mehreen S. Dharsee
Regulatory Fellow
Sanofi

Dana Lee
Pharmacovigilance Fellow
Sanofi

Board 3
Investigational Study to Determine Best Practices for Submitting Premarket Clinical Data to Support Product Claims

Kanchana Iyer
Senior Regulatory Affairs Specialist
PENTAX Medical

DAY TWO | FRIDAY, FEBRUARY 24

7:00AM-4:00PM	**Registration**
7:00-8:00AM	**Continental Breakfast, Exhibits, and Networking**
7:15-8:00AM	**DIA Regulatory Affairs Advertising and Promotion Working Group Benchmarking Survey** Participate in an exchange of ideas regarding the inaugural DIA Regulatory Affairs Advertising and Promotion Working Group Benchmarking Survey created to identify current committee best practices and review areas for continuous quality improvement. Join us, contribute, and takeaway opportunities to enhance your organization! **Speakers** **Kimberly Belsky, MS** Senior Director, Regulatory Intelligence, Regulatory Affairs Mallinckrodt Pharmaceuticals **Chris DeFusco, PhD, RAC** Senior Director, Commercial Regulatory Affairs Mallinckrodt Pharmaceuticals
8:00-8:05AM	**Welcome to Day Two**
8:05–8:35AM	**Takaways from Day One and Q&A** **Session Chair** **Glenn Byrd, MBA, RAC** Senior Director, Specialty Care Promotional Regulatory Affairs AstraZeneca
8:35-9:35AM	**Session 7** Mobile Apps – When Are They Promotions, When Are They Regulated Devices? Mobile apps are taking over the medical industry but when are they considered a medical device versus a promotion product? The FDA is choosing to focus on a small subset of mobile apps that meet the regulatory definition of "device" and that "are intended to be used as an accessory to a regulated medical device, or transform a mobile platform into a regulated medical device." If an app is NOT a medical device and its promotional labeling then what are the considerations when creating a mobile app about promotional labeling? This session will take a close look at how mobile apps are used within the industry, review FDA mobile app guidances, and feature a panel discussion including a mobile app provider. **Session Chair** **Tracy Rockney, JD** Co-Founder and Managing Partner OneSource Regulatory **Panelists** **Al D'Alonzo, PhD, MS** Vice President, Promotion Compliance Otsuka Pharmaceutical Development & Commercialization **Tracy Rockney, JD** Co-Founder and Managing Partner OneSource Regulatory
9:35-10:00AM	**Refreshments, Exhibits, and Networking Break**

Thanking our Media Partner: PharmaVOICE

DAY TWO | FRIDAY, FEBRUARY 24

10:00-11:30AM

Session 8: Breakout Sessions

TRACK A

Ad-Promo's Role in the Adoption of Technology across the Organization

Regulatory professionals specializing in advertising and promotional labeling are being asked to take on tasks well beyond the traditional review of promotional tactics. This session looks at some of the expanded responsibilities ad-promo professionals are tackling including:

- The successful transition to eCTD ad promo submissions
- Development, rollout, and maintenance of effective policies and guidelines for compliant use of new and emerging technologies
- Assisting in the outreach to partner companies and startups as part of corporate initiatives to drive innovation

Session Chair
Dale Cooke
Owner
PhillyCooke Consulting

Speakers
Jim Vigil
Director, Regulatory Affairs, US Advertising and Promotion
AbbVie

Ami Patel
Senior Counsel
Johnson & Johnson

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

TRACK B

Deep Dive: Digital Tactics

Join this team of subject matter experts to explore a mock digital case study of ARBITRAER (misvastatium), a drug approved to treat seasonal allergies. Today, pharmaceutical companies must learn to meet customers where they are in the moments they need us most. Based on the needs within the marketplace and shift in customer expectations due to the constantly evolving digital and social media landscape, a brand marketing manager will engage the digital agency to create a Facebook page and affiliated posts, a mobile optimized banner ad, and a YouTube post.

With the help of a promotional regulator, the team will explore the regulations that govern these unique digital activities, as well as evaluate previous compliance letters and guidance documents to help inform their participation in this space.

In addition, the team will address the infrastructure needed within their fictitious company, including key partnerships, education, and standard operating procedures/guardrails.

At the end of this session, you will better understand:

1. What is needed to bring a digital campaign to market
2. Who the subject matter experts are and when to engage their expertise
3. Unique challenges of three core digital tactics
4. How to execute the tactics in a compliant manner, utilizing core regulatory principles

Session Chair
Rosemarie Carey
Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP

Panelists
Rosemarie Carey
Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP

Josephine Secnik, MBA, MS
Principal Advisor - Regulatory
Eli Lilly and Company

Jeanne Greene
Program Director, Digital
IMRE

Jennifer McIlvaine
Marketing Leader
AstraZeneca

11:30AM-1:00PM

Round Table Discussion Luncheon

Approximately 30 minutes into the expanded lunch period, leaders within the Advertising and Promotion Regulatory Affairs community will lead each table in discussions started during their sessions. Discussion leaders will examine key outcomes from sessions while also encouraging you to connect with colleagues and share experiences and questions.
(Sign up at the registration desk.)

DAY TWO | FRIDAY, FEBRUARY 24

1:00-2:10PM

Session 9: Breakout Sessions

TRACK A

Considerations for Developing a Productive Advertising and Promotion Team

Interested in learning about approaches to recruiting talent and sustaining a highly successful advertising and promotion team? Hear recommendations from other senior leaders on identifying key qualities sought for these roles, training programs offered, and systems, tools, and resources developed to support these cross-functional teams. Learn tips on advising team members on how to construct development plans to proactively manage careers.

Session Co-Chairs

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

Tammy J. Phinney, MSc
Senior Director, Regulatory Affairs
Biogen Idec Inc.

Panelists

Nahrin Marino
Deputy General Counsel-Regulatory
Astellas Pharma US, Inc.

Tara Barbanell
Director, Regulatory Promotion
Amgen

Kathleen Taylor
Principal Clinical Research Scientist
Eli Lilly and Company

TRACK B

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

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.

Session Chair

Paul Savidge, JD, MBA
Senior Regulatory Counsel
Spark Therapeutics, Inc.

Panelists

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

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

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

Denise Rieker-Clark, MS
Director, Regulatory Affairs
Sanofi Pasteur

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

2:10-2:30PM

Refreshments, Exhibits, and Networking Break

2:30-3:30PM

Session 10
Patient Support Programs

Patient Support Programs play an important role in assisting patients with their prescribed medication and contributing to a brands' retention strategies. The programs can add value by ensuring patients obtain access to the therapy, correctly use the therapy, and continue to stay on therapy throughout all stages of their disease progression. However, communication in this area can be complicated as companies want to provide information without coming across as promotional. This session will explore industry best practices and nuances related to communicating compliantly in patient support programs.

Session Chair
John Paul Marcus, PharmD
Regulatory Affairs, Neuroscience Ad/Promo
AbbVie

Panelists
Melissa Fellner, MBA
Associate Director Access Services Strategy
AstraZeneca

John Paul Marcus, PharmD
Regulatory Affairs, Neuroscience Ad/Promo
AbbVie

Sanjay Narayan, JD
Senior Counsel
AbbVie

Marissa Fuller, MHS
Associate
Covance

3:30-4:00PM

Closing Session: FDA in the Trump Administration

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

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

Michael McCaughan, FACP
Founding Member
The RPM Report/Prevision Policy

4:00PM

Conference Adjourned