eXl events

SEPTEMBER 23–25, 2019
HYATT REGENCY MORRISTOWN // MORRISTOWN, NJ

7TH

PROMOTIONAL REVIEW COMMITTEE COMPLIANCE & BEST PRACTICES

The recognized leading event for uniting cross-team expertise, maximizing quality oversight during review, and maintaining regulatory compliance in all multimedia promotional materials

ALL-NEW STRATEGIES

- Latest analysis about off-label messaging and scientific exchange after recent 1st Amendment court decisions
- Detailed strategies for improving your promotional review approach for social networks and adaptive websites
- Best practices for communications with payers and managed markets
- Troubleshooting ad/promo submissions through the eCTD gateway

2 INTERACTIVE WORKSHOPS!

Leverage Under Today's Regulatory Environment

Training and Development for Ad Promo Professionals

Conference Chair:

Gary Wieczorek,
Director, Regulatory Affairs,
ABBVIE

Richard Lem,
Associate Director, Regulatory Affairs – Advertising and Promotion,
BAYER HEALTHCARE

Ian DeMeritt,
Medical Director,
FINGERPAINT

Linda Pollitz,
Senior Director, Regulatory Affairs, Advertising and Promotion,
ALKERMES

Kate Ho,
Manager and Regulatory Affairs Advertising Promo
TESARO

Dan Zavodnick,
General Counsel,
KEDRION BIOPHARMA

Anita Kachappilly,
Manager, Regulatory Affairs, Advertising, Labeling, and Promotion,
BIOGEN

Nicole Lare,
Associate Director,
CELGENE

"These events are always useful for networking with industry peers but I found the content of this meeting particularly informative this year. Worthwhile topics and excellent presentations."
–Manager, Commercial Services, **GRIFOLS**

"Dynamic, knowledgeable presentation that used real-life/relatable examples."
– Marketing Operations Specialist, **SUNOVION PHARMACEUTICALS**

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Dear Colleague,

FDA regulations and the latest guidance's finalized a flexible policy for how drug and device manufacturers can discuss payments, outcomes, and healthcare data with payers and other audiences with expertise in drug prescribing and coverage. This now has officially set the tone for what the FDA is looking for and what is not acceptable. To help ensure their promotions the need to design, advance, and constantly modify, your promotional review committee is of the utmost importance.

With these new regulations, promotional review professionals face new challenges from the rapid growth of social media, to the popularization of online regulatory submission, to the still-developing shockwaves released by 1st Amendment court decisions about off-label communication. As these new challenges arise, PRCs must always be able to gather and organize input from multiple disciplines, make their deadlines, and ensure the review process moves smoothly.

The **7th Promotional Review Committee Compliance and Best Practices** delivers a multi-stakeholder perspective on the new guidelines, the challenges of marketing pharmaceuticals, and new technologies for the promotion of FDA regulated products. At this year's event, we can focus on how pharmaceutical organizations are adapting in the 2019 PRC climate.

I look forward to meeting you in September!

Sincerely,

Jenna Castellano

Jenna Castellano | Conference Production Director
ExL Events, a division of Questex, LLC

WHO SHOULD ATTEND

This conference is designed for pharma, biotech, and medical device professionals with responsibilities in the following areas:

- Promotion Review / Promotional Review / PRC
- Material / Clinical Review
- Regulatory Promotion and Advertising
- Regulatory Affairs / Regulatory Process / Compliance
- Labeling
- Medical Affairs / Medical Review
- Program Review / Review Operations / Program Review Operations
- Editor / Editorial Review / Copy Editing
- Medical Information
- Medical Communications / Medical Information / Medical Science Liaison / Director
- Marketing / Marketing Operations / Marketing Communications / Marketing Services
- Commercial Operations
- Brand Manager / Product Manager / Brand Marketing
- Legal Affairs / Counsel / Regulatory Counsel

This event is also of interest to:

- CRM / Data Management Software Suppliers
- MLR Process Vendors and Facilitators
- Advertising / Marketing Agencies
- Regulatory Consultants
- Medical Writing Firms
- Law Firms

Hyatt Regency Morristown
3 Speedwell Avenue
Morristown, NJ 07960

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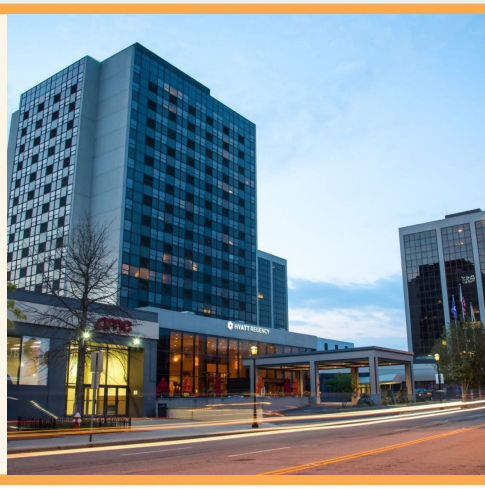

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To Register, Call 201 871 0474 or Click Here

SEPTEMBER 23, 2019 // WORKSHOP DAY

8:30 **Registration and morning continental breakfast**

9:00 **MORNING WORKSHOP: The Evolving Role of the Promotional Review Process: How to Navigate Regulatory, Compliance and Legal Challenges in Today's Environment and Beyond**

In today's complex and uncertain legal environment relating to the pharmaceutical industry, regulatory and healthcare compliance related risks continue to be of significant concern. Given the overlapping sources of oversight relative to pharmaceutical industry activities, the importance of the internal promotional review process has grown significantly over the past several years. The traditional role of applying medical, regulatory and legal standards in reviewing and approving promotional messaging has expanded as new sources of data and analysis have been embraced by the FDA as mandated by the 21st Century Cures Act. The responsibility to ensure that information contains "fair balance" and is "truthful and non-misleading" in communicating with HCPs now requires a new examination of the review and approval function and establishing revised internal standards to address developing regulatory and compliance issues where definitive regulatory guidance has yet to be developed while enforcement continues. This interactive workshop will focus on the risks and best practices associated with communicating with HCPs based on both traditional and developing data sources.

The workshop will also analyze the internal review process to help the attendees:

- Understand the FDA's new focus on expanding regulatory oversight with regard to promotion of products in evolving areas such as the rise of digital health technologies
- Examine the developing interest in utilizing Real World Evidence (RWE) in combination with traditional clinical study data in both regulatory filings and product promotion while government guidance remains to be finalized
- Address areas such as Quality of Life (QOL) in a compliant manner
- Discuss methods to substantiate claims regarding a drug or medical device's economic impact
- Distinguish between product promotion and disease state information in communicating with HCPs during the critical pre-approval period

Howard L. Dorfman, *Adjunct Professor,* **SETON HALL UNIVERSITY SCHOOL OF LAW** *and Founder,* **H.L. DORFMAN PHARMACEUTICAL CONSULTING, LLC**

12:00 **Morning Workshop Concludes**

1:30 **Registration**

2:00 **Afternoon Workshop: CASE STUDY: Training and Development for Ad/Promo Professionals**

It is important to have Promotional Review Committees who are knowledgeable of the stringent legal, medical, and regulatory requirements for an organization. Aligning and training members to understand specific roles and processes in your committee can ensure a more efficient review process

- Recognize how professionals in the industry train themselves and showcase their career development
- Understand the importance of establishing the role of your review committee
- Address the importance of prioritizing timelines and communication while applying "soft-skills"

Janet Gottleib, *Executive Director, Medical Promotional Review,* **ALLERGAN**

Jimmie Overton, *VP Global Medical Scientific Information,* **ALLERGAN**

5:00 **Afternoon Workshop Concludes**

SEPTEMBER 24, 2019 // MAIN CONFERENCE DAY ONE

8:30 **Registration and Continental Breakfast**

9:00 **Introduction From Conference Chairperson**

Gary Wieczorek, *Director, Regulatory Affairs,* **ABBVIE**

9:15 **PANEL: Take Control of Medical, Legal and Regulatory to Establish PRC Meetings**

- Explore best practices and challenges for marketing initiatives and industry dynamics
- Review how recent court cases impact off-label communications with drugs
- Consider key legal and regulatory activity to identify trends on key legal and regulatory strategies to avoid violations

Jill Charbonneau, *Director Regulatory Affairs,* **HARMONY BIOSCIENCES**

Denice Simon, *Assistant General Counsel,* **TAKEDA PHARMACEUTICALS**

10:00 **Are you optimally orchestrating your digital commercial content from creation to expiry?**

Victoria Marsh, *Director of Content Offerings Management,* **IQVIA**

Ted Zobel, *Lead Solutions Engineer,* **IQVIA**

10:45 **Networking Break**

11:15 **A Walk in Their Shoes: A Look at PRC Meetings From the Marketing Agency's Perspective**

- We're all on the same team: collaborating with your agency to find common ground
- The importance of communicating clear standards and providing direct feedback
- Whose voice is that? Who from the agency may be on the line
- Tips for improving the agency/PRC relationship
- What to do when the agency just doesn't seem to get it

Ian DeMeritt, *Medical Director,* **FINGERPAINT**

12:00 **Address and Implement Best Practices for Promotional Use**

- Understand Real-World Evidence and Real-World Data on practices for promotional use to avoid false and misleading communications
- Compare and contrast the Lanham Act and 1st Amendment issues
- Off-Label Use — the fine line between illegal promotion and useful information and pricing issues

Linda Pissott Reig, *Co-Chair,* **BIONJ LEGAL, COMPLIANCE, & REGULATORY GROUP;** *Adjunct Professor, Management and Global Business,* **RUTGERS BUSINESS SCHOOL**

12:45 **Luncheon**

1:45 **Can Agility and Risk Management Co-Exist?**

Brand teams are under significant press to be more responsive to customer information needs. That's why Commercial is increasingly turning to Agile Frameworks using Scrum and Sprints to innovate more quickly. Agile methodologies will require reviewers to make more rapid decisions about content compliance. Is it possible to manage risk in a fast moving ad/prom review process?

- Describe the Agile methodology and its role in speeding up innovation through quicker decision-making
- Explore the challenges and opportunities of applying Agile to the promotional review process
- Formulate strategies and tactics that balance faster decision-making with regulatory compliance requirements

Ilyssa Levins, *President,* **CENTER FOR COMMUNICATION COMPLIANCE**

2:30 **The Rise of New Technologies and Best Practices for Applying FDA Promotional Guidelines**

Not since the late 90s have pharmaceutical companies been bombarded with so many new technologies for interacting with their patients - from digital therapeutics, to wearables, chatbots, or voice-enabled technologies, such as Amazon Echo.

- Understand how new technologies are used in the industry
- Manage considerations for MLR to keep in mind when applying FDA promotional guidelines

Linda Pollitz, *Senior Director, Regulatory Affairs, Advertising and Promotion,* ALKERMES
Tiffany Mura, *Director, Consumer and Digital Marketing,* ALKERMES

3:15 **Networking Break**

3:45 **Models of Success for High Level Leadership Styles with Cross-Functional Collaboration**

- Address the responsibilities Senior Management takes to ensure the promotional review process runs efficiently especially during a launch
- Prioritize what metrics need to be collected, and what goals need to be adopted by cross-functional members
- Empower employees to make tactical decisions to take appropriate risks
- Focus on AbbVie's leadership behaviors and describe how they are applied in making promotional review decisions

Gary Wieczorek, *Director, Regulatory Affairs,* ABBVIE

4:30 **The Sound of Silence: Build a Way Forward When Lacking FDA Enforcement Cases**

Often you get most of your cues from FDA issuing warning letters — but what can you do if they stop sending them? Lack of enforcement makes it hard to determine their thinking and plan accordingly.

- Figure out risk/benefit analysis and how aggressive to be
- Anticipate that enforcement levels will rise
- Gather expertise from regulatory insiders when charting a way forward

Alexander Zachos, *Lead, Associate Director, U.S Regulatory Advertising and Promotion,* SHIRE

5:15 **End of Day One**

SEPTEMBER 25, 2019 // MAIN CONFERENCE DAY TWO

9:00 **Chairperson's Recap of Day One**

Gary Wieczorek, *Director, Regulatory Affairs,* ABBVIE

9:15 **PANEL: Diversify the Use of Social Media and Advertising Promotion**

- Enhance and develop the use of Snapchat for your healthcare organization
- Monitor commenting and posting on social media — learn best practices to respond to comments
- Recognize how campaigns need to adapt for new media

Kate Ho, *Manager and Regulatory Affairs Advertising Promotions,* TESARO BIOSCIENCES
Anita Kachappilly, *Manager, Regulatory Affairs — Advertising, Labeling, and Promotion,* BIOGEN

10:00 **Learnings From FDA Ad\Promo Enforcement Actions and Trends**

FDA uses a "risk-based" approach to target advertising and promotional activities that have a potential impact on health and patient safety. Understanding these current areas of focus can provide key learnings and opportunities to enhance the internal processes and decision-making.

- Identify current areas of focus in enforcement letters (untitled and warning letters)
- Gain insights into enforcement trends and new areas of risk
- Advance strategic thinking in today's regulatory environment

Kimberly Belsky, *Executive Director, Regulatory Policy and Intelligence, Regulatory Affairs,* MALLINCKRODT PHARMACEUTICALS

10:45 **Networking Break**

11:15 **PANEL: Create Better Partnership Between Medical, Regulatory, and Commercial Operations**

Good communication with reviewers and collaboration between reviewers and all key stakeholder from marketing/advertising teams ensures that these materials are accurate, efficient, and risk-adverse.

- Balance efforts between reviewers, marketing, agencies to produce focused promotional materials
- Develop KPIs developed around MLR teams to help target opportunities for accuracy and efficiency
- Communicate properly between teams to have the process at a good pace from sales training to the review cycle

Richard Lem, *Associate Director, Regulatory Affairs Affairs, Advertising and Promotion,* BAYER HEALTHCARE
Nicole Lare, *Associate Director,* CELGENE
Dan Zavodnick, *General Counsel,* KEDRION BIOPHARMA

12:00 **Company Perspectives on Implementing the "Consistent With Label and Payer Guidances"**

- Understand the communications of the HCEI regarding prescription drugs and medical devices
- Provide FDA recommendations for firms to help ensure compliant information to payers
- Highlight risk mitigation in grey areas and how far you can push these boundaries

Anthony Molloy, Esq, *Vice President, Legal and Compliance, General Counsel, Deputy Compliance Officer,* PACIRA PHARMACEUTICALS
Alex Celius, *Senior Compliance Associate,* PACIRA PHARMACEUTICALS

12:45 **Luncheon**

1:45 **Interactive Session: Learn OPDP Expectations During a Sample Regulatory Review Scenario and New Regulations**

OPDP reviewers and outside counsel provide crucial feedback on your commercial pieces. By sitting in and learning from the thought processes of people familiar with OPDP's review of your promotional materials, you can better understand how they take claims apart and how regulatory analysis may come down against you ifyou don't have the right evidence. This interactive workshop enables you to internalize and work with OPDP expectations during a real-time "mock" review meeting.

- Clarify where your expectations of labeling and promotional information differ from those of OPDP reviewers
- Zero in on areas where terminology use may cause confusion from a regulatory perspective
- Gain an understanding of truthful, balanced, and accurately communicated information
- Anticipate the level of investment in both time and resources required for a successful review

Nneka Onwudiwe Pharm.D., Ph.D., MBA, *Founder and Chief Executive Officer,* PHARMACEUTICAL ECONOMICS CONSULTANTS OF AMERICA (PECA) LLC
Keren Tenenbaum, *VP and Assistant General Counsel, Head of Legal, Salix,* BAUSCH HEALTH
Cristina Masseria, *Methods and Capabilities Lead,* PFIZER

2:30 **Eliminate Error Sources in E-Detailing**

- Align your team's understanding of how e-detailing applies to in-person communicators, computer displays, and other media
- Ensure that all stakeholders have the same definition of the term
- Watch for problems as you move into new systems

Doreen Morgan, *VP of U.S Regulatory Affairs and Quality Assurance,* LEO PHARMACEUTICALS

3:15 **CASE STUDY: Dive Into the PRC Process and New Technology**

- Formulate and implement regulatory strategies and plans to achieve efficient and competitive product development
- Collaborate with other project management teams to have a better understanding of the SOP
- Understand how organizations and promotional reviews are reviewing new projects and strategic technology and social media systems

Kathy Tavakoli, *Regulatory Affairs Advertising and Promotion,* LUPIN PHARMACEUTICALS

3:45 **Chairperson's Closing Remarks**

4:00 **Conference Concludes**

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Conference + 1 Workshop	$2,295
Conference + 2 Workshops	$2,495
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Conference	$2,095
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