May 15-17, 2019

Kimpton Hotel Palomar Chicago || Chicago, IL

6th

PROMOTIONAL REVIEW COMMITTEE COMPLIANCE & BEST PRACTICES *MIDWEST*

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

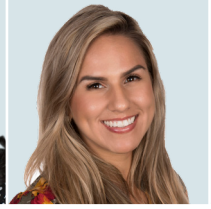
Nneka Onwudiwe
Regulatory Reviewer
FDA, USA

Nan Clarke
Manager, Promotional Marketing Operations and Compliance
ABBVIE

Bradley Coushman
Vice President
ELEMIS CORPORATION

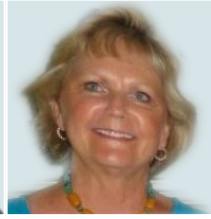
Heather Goldstein
Marketing Services Effectiveness Manager
TAKEDA

Kim Maney
Senior Counsel
GLAXOSMITHKLINE



Anghela Gonzales
Manager, Program Review Operations,
GENENTECH

Rebecca Burns
Medical Affairs Manager
ARBOR PHARMA



Ilze Antons
Senior Director, Regulatory Affairs
LUNDBECK

ALL-NEW strategies on the biggest technical and teamwork challenges

- Keep Social Media Approaches Diverse and Flexible
- Adjust PRC Operations to Mergers and Acquisitions
- Implement CAPAs for Promotional Review
- Tier Your Review Process Based on Complexity
- Formalize SOPs and Document Management Methods for Newer Teams
- Train for Forecasting and Managing High Material Volume
- Understand Physician Concerns Regarding Data Consistent With Labels
- Optimize Your Use of Experts in Rare Disease Campaigns

PLUS! INTERACTIVE WORKSHOP: Learn OPDP Expectations During a Sample Regulatory Review Scenario

"The networking and sharing of ideas was valuable! It is so great to talk with fellow PRC members and learn some new best practices."
—Associate Director, Promotional Regulatory Affairs, **ASTRAZENECA**

"I was very pleased with the information provided at the event. I came away with valuable resources to use, new contacts, a better understanding of additional FDA guidances available, and better grasp of HEOR/HCEI."
—Regulatory Affairs Specialist, **U.S. WORLDMEDS**

"Eye opening and new information, I learned new ideas and practices I was not familiar with"
—Regulatory Regional Lead, **JANSSEN**

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To Register, Call 201 871 0474 or Click Here

Dear Colleague,

With so many perspectives and such tight deadlines, promotional review committees are tough to manage under even the best circumstances. And more frequently, PRC professionals are facing new and uncertain challenges due to corporate restructuring, high staff turnover, and ever-evolving regulatory guidelines for new media.

ExL's Promotional Review Committee Compliance & Best Practices — Midwest conference is the leading industry event for improving PRC teamwork and speed while maintaining expertise even with changes in team composition and regulatory expectations. No other event offers such in-depth technical and operational strategy from such a large faculty of your peers!

Now in its sixth year, this event has grown into a three-day conference to cover more ground than ever! Built off your feedback, this year's agenda provides new strategies for:

- **Complexity-based tiering** of PRC responsibilities
- Maintaining team skills and readiness during **mergers, acquisitions, and divestitures**
- Managing **document access and accuracy** in spite of regular turnover
- Efficiently leading PRCs amidst **high material volume**
- **Developing CAPAs** to gauge committee performance

Plus, by popular demand, this year's event features two in-depth, interactive workshops on **learning OPDP expectations in sample review scenarios** and **forecasting and managing increased material volume!**

I look forward to seeing you in Chicago this spring!

Sincerely,

Jenna Castellano

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

"Great discussions. I heard many different perspectives and gained insights on PRC improvement."
—Senior Manager, Promotion Compliance, **OTSUKA**

"Very pertinent to my current PRC activities and process questions."
—Promotional Review Management Associate, **TAKEDA**

WHO SHOULD ATTEND

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

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

Kimpton Hotel Palomar Chicago
505 N. State St
Chicago, IL 60654

To make reservations, please call 1-800-546-7866 and request the negotiated rate for **HM8.** You may also make reservations online at: https://bit.ly/2H0SJyl . The group rate is available until **April 23, 2019**. Please book your room early, as rooms available at this rate are limited.

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SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promo-tional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

To Register, Call 201-871-0474 or Click Here

WEDNESDAY, MAY 15, 2019 // WORKSHOP DAY

8:30 **Registration**

9:00 **MORNING WORKSHOP: Learn OPDP Expectations During a Sample Regulatory Review Scenario**

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 if you 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 understanding of truthful, balanced, and accurately communicated information
- Anticipate the level of investment in both time and resources required for successful review

Nneka Onwudiwe, *Senior Scientific Reviewer, OPDP,* **FDA**

Keren Tenenbaum, *Assistant General Counsel,* **PFIZER**

Cristina Masseria, *Methods and Capabilities Lead,* **PFIZER**

Renee Ambrosio, *Director, Advertising and Promotion, Regulatory Affairs,* **MERCK**

12:00 **Morning Workshop Concludes**

1:30 **Registration**

2:00 **AFTERNOON WORKSHOP: Create Tools and Training to Efficiently Forecast, Manage, and Allocate Volume**

A good training asset will bring stakeholders together and clarify processes and systems that might be confusing even to team veterans. New tools for in-person training (as opposed to digital training) can help deal with large volumes of material, improve process understanding, and instill a "right-the-first-time" mentality into project owners and reviewers.

- Understand where your company's PRC training methodologies rank among your peers
- Forecast and set expectations based on promotional volume, resources, and the length of the review process
- Clarify the importance of timelines and triggers for potential setbacks
- Emphasize coordinator involvement at every step

Heather Goldstein, *Marketing Services Effectiveness Manager,* **TAKEDA**

Anghela Gonzalez, *PRO Associate Manager,* **GENENTECH**

5:00 **Afternoon Workshop Concludes**

THURSDAY, MAY 16, 2019 // MAIN CONFERENCE DAY ONE

8:00 **Registration and Continental Breakfast**

8:45 **Introduction From Conference Chairperson**

NEW REGULATIONS, NEW INDICATIONS, NEW MEDIA

9:00 **Navigate the Intersection of Medical and Regulatory in Product Education**

Educating and engaging audiences, especially in less-well-known conditions or diseases, can be challenging. As PRC reviewers, we see the promotional side of disease education, but what are our colleagues in medical doing, and where are there potential areas for blurred lines?

- Assure "separation of church and state"
- Specify the challenges when medical gets involved with proactive education
- Predict the coming trends for disease education

Ilze Antons, *Senior Director, Regulatory Affairs,* **LUNDBECK**

9:45 **Keep Your Social Media Approaches Diverse and Flexible**

PRCs can find some social networks to have far more comfortable interfaces than others. By learning from real-life examples and studying the history of FDA enforcement letters and guidances regarding social media, PRCs can modernize their outreach while lowering the risk of regulatory intervention.

- Grapple with social media's space limitations on compliant promotions
- Examine case studies of social media campaigns in the public domain
- Recognize how campaigns need to be adapted for new media

Sandra Vladisavljevich, *Senior Director, Regulatory Advertising and Promotion,* **TAKEDA**

10:30 **Networking Break**

11:00 **PANEL: Develop QC Processes for Promotional Review**

Your operations team ensures the quality of final materials. It enables effective collaboration between editors and reviewers, marketing teams, and coordinators. There are different points in the process where editors' input can be most effective.

- Make sure editors work closely with reviewers and marketers
- Use a "check changes" process to verify that reviewers' edits were applied
- Ensure readability, content flow, and correct grammar and punctuation
- Share an in-house style guide with agencies

Moderator: **Rebecca Burnett,** *Executive Director, Head of Strategic Services,* **FRAMEWORK SOLUTIONS**

11:45 **Adjust PRC Operations and Expectations to Mergers, Acquisitions, and Purchases**

As pharma companies purchase each other, are purchased, or purchase additional assets, it is tremendously difficult for PRC teams to navigate the changing rosters and corporate expectations. Managers must be able to work within different disease areas, messaging goals, changing risk tolerance and changing leadership.

- PRC strategy for a successful merger, acquisition or purchase of a marketed product
- Manage expectations during rebranding and/or changes due to risk tolerance
- Recognize when additional levels of review are necessary as priorities change

Rebecca Burns, *Medical Affairs Manager,* **ARBOR PHARMACEUTICALS**

12:30 **Luncheon**

To Register, Call 201-871-0474 or Click Here

OPTIMIZING PRC TRAINING AND TEAMWORK

1:30 Properly Sequence Input From Medical Reviewers

Medical reviewers may have different priorities and backgrounds than other PRC members. They will offer various means of representing findings which your leadership must be prepared to mesh with the rest of the group.

- Work with medical reviewers from a legal/regulatory/content author perspective
- Establish the level of evidence acceptable to support particular claims
- Anticipate the priorities of medical reviewers, so a unified PRC voice is possible

Alexander Shaw, *Manager, Medical Information,* **ALKERMES**

2:15 Select and Implement CAPAs for Promotional Review

In 2018, a new industry-working group on PRC, Corrective and Preventive Action (CAPA), started to explore how different organizations respond to errors in material that's been released for use. By learning about different models of CAPA structures, processes, and documentation, PRC professionals will gain insights into developing best practices.

- What's the value of having a CAPA team/structure?
- Discuss the pros and cons of typical PRC CAPA structures
- Impact assessment — is it a mud puddle or a sink hole?
- Walk through a scenario — who does what, when, and what documentation is required?

Nan Clarke, *Manager, Promotional Marketing Operations and Compliance,* **ABBVIE**

NAN KNICKERBOCKER CQM RAC, *Associate Director, Regulatory Affairs, U.S. Advertising and Promotion,* **ABBVIE**

3:00 Networking Break

3:30 PANEL: Transmit Consistent Metrics and KPIs to Process Owners and Partners

A major challenge facing PRCs is to monitor how long pieces take to get through review, figure out where bottlenecks are, and speed up the process as necessary. Particularly during major launches, operations team members must emphasize tracking every piece and reporting to senior management regarding where they stand in relation to benchmarks for major initiatives.

- Recognize methods for accelerating time to market from approval to dissemination
- Determine how outsourced and vendor partnerships can help in marketing operations
- Review real applications of KPIs

MODERATOR: **Jason Benagh,** *Manager, Marketing Operations,* **ALKERMES**

4:15 Manage Digital Assets for Approval and Submission of Templated or Dynamic Materials

Some materials, such as invitations or conference posters, may be based on templates where the regulated content remains fixed, and the only changes are to minor information such as event dates. What are the most efficient means for developing, archiving, and managing compliant templates? And how can you determine the limits of acceptable changes to pre-approved content?

- Identify the team members and methods best suited for Digital Asset Management
- Learn from other industries where templated content is reused
- Maintain fair balance when modifying templated materials

Bradley Coushman, *Vice President,* **ELEMIS CORPORATION**

5:00 Day One Concludes

FRIDAY, MAY 17, 2019 // MAIN CONFERENCE DAY TWO

8:00 Registration and Continental Breakfast

8:45 Chairperson's Recap of Day One

9:00 Tier Your Review Process Based on Material Complexity

- Set clear expectations on who determines complexity and by which criteria
- Analyze successful attempts at tiering
- Emphasize flexibility due to the likelihood of staff turnover

Kim Maney, *Senior Counsel,* **GLAXOSMITHKLINE**

9:45 PANEL: Leadership Tactics to Improve PRC Efficiency

PRC meetings can be long and frequent, taking up a substantial amount of time for all people involved, with limited resources. Committee stakeholders should prioritize efficient PRC processes, so participants' time is best utilized. This includes clarifying roles and responsibilities and establishing whether one or two committees are needed for reviewing promotional and non-promotional items.

- Discuss the use of manual and computer-based systems
- Ensure that materials sent to PRC are actually ready for review
- Benefit from an established elevation process

Moderator: Steve Gersten, *Vice President, General Counsel,* **DYNAVAX**
Brad Patrick, *Division Counsel,* **ABBVIE**
Bill Benvenuto, *VP Legal Affairs and Chief Compliance Officer,* **RETROPHIN**
Chirsti Bruce, *Senior Manager MLR Operations and Platforms,* **SANOFI**

10:30 Networking Break

11:00 Strategies to Mitigate Conflicts and to Play and Fight Fair in PRC

With so many sides to PRCs, there is a difference in how interests and objectives play out based on personalities, approaches, and agendas. The most crucial key to successful PRC is overlooking the dynamics and interpersonal differences and characters in each meeting and as a whole .

- Understand best practices to be efficient and objectives of all parties
- Approach the commercial interest vs. medical, legal and regulatory
- Establish efficient and product approaches from a legal and compliance perspective

Peter Lee, *Vice President, Chief Compliance Officer,* **HERON THERAPEUTICS**

11:45 PANEL: Fine-Tune Your Training Methods for Marketing Agencies

Marketing agencies might not at first understand your specific requirements, but dedicated coordinators can be quite successful at training them. If agencies give pushback on your PRC's comments, there needs to be a set process for handling and correcting them.

- Review the usefulness of agency report cards
- Rank preferred agencies based on knowledge and willingness to learn partner processes
- Empower coordinators to make clear when agencies are being more of a hindrance than help

Robert Masi, *Associate PRO Manager,* **GENENTECH**

12:30 Luncheon

1:30 Eliminate Error Sources in E-Detailing

With so many different platforms available, as you transfer old assets and move all of your sales representatives to a single new system, there is a risk of sending mixed messages. To keep watch over the non-personal promotions that your representatives conduct directly with physicians, you must broaden your focus beyond just what you send out.

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

Christi Bruce, *Senior Manager MLR Operations and Platforms,* **SANOFI**

2:15 Recognize When Third-Party Consultants Can Assist With Determining PRC Course of Action

When PRC professionals face strong differences of opinion, third-party consultants may be able to provide helpful insights into how regulatory guidelines are interpreted and how they should apply to your work. It is worth maintaining a good rapport with them even if your team does not accept their recommendations.

- Determine the best regulatory liaison candidates based on your product portfolio and team dynamics
- Gain a clearer picture of what other companies are doing
- Pair any rejections of their recommendations to specific wording from regulatory guidelines in order to keep relations smooth

3:00 Conference Concludes

WAYS TO REGISTER

Phone: 201-871-0474

Online: Click Here

@ Email: register@pmaconference.com

Mail: PMA Conference Management
POB 2303
Falls Church VA 22042

Fax: 201 871 0474

Registration fees for attending ExL's 6th Promotional Review Committee Compliance & Best Practices — Midwest conference:

EARLY BIRD PRICING *(Register Before Friday, March 29, 2019)*	
Conference	$1,795
Conference + 1 Workshop	$2,095
Conference + 2 Workshops	$2,295
STANDARD PRICING	
Conference	$1,995
Conference + 1 Workshop	$2,295
Conference + 2 Workshops	$2,495
ONSITE PRICING	
Conference	$2,195
Conference + 1 Workshop	$2,495
Conference + 2 Workshops	$2,695

GROUP DISCOUNT PROGRAM

Offers may not be combined. Early Bird rates do not apply. To find out more on how you can take advantage of these group discounts, please call 201-871-0474.

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