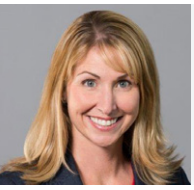
THE ONLY INDUSTRY CONFERENCE TO EMPHASIZE TEAMWORK, SPEED, AND REGULATORY AWARENESS AMONG ALL PRC MEMBERS!

6TH

# PROMOTIONAL REVIEW COMMITTEE COMPLIANCE & BEST PRACTICES

***Uniting Cross-Team Expertise, Maximizing Quality Oversight During Review, and Maintaining Regulatory Compliance in All Multimedia Promotional Materials***

**SEPTEMBER 24-26, 2018 // HYATT REGENCY MORRISTOWN // MORRISTOWN, NJ**



**PFIZER** Resolves Unanswered Questions About Off-Label Information
**Cecilia Bakker**
*Assistant General Counsel*

**MALLINCKRODT** Prevents Miscommunications With Marketing Agencies
**Joyce Pearl**
*Senior Manager, Marketing Services*

**OTSUKA** Clarifies Social Media Comment Strategy When FDA Signals Are Rare
**Stephanie Jameison**
*Director, Global Regulatory Affairs, Promotion Compliance*

**PTC THERAPEUTICS** Maintains Compliance in Reprints and Textbooks
**Alan Bergstrom**
*Commercial Regulatory Affairs*

**ALKERMES** Prepares PRCs to Cope With Black Box Warnings
**Linda Pollitz**
*Senior Director, Regulatory Affairs, Advertising and Promotion*

## ALL-NEW STRATEGIES

- Formalize the Use of References in Promotional Pieces
- Cope With Frequent Team Turnover
- Prioritize PRC Agility to Improve Patient Value
- Set Firm Boundaries on Review Timelines
- Empower Editors to Boost PRC Speed

## INTERACTIVE WORKSHOP:

LEARN OPDP EXPECTATIONS DURING A SAMPLE REGULATORY REVIEW SCENARIO

**Nneka Onwudiwe**
*PRO/PE Regulatory Reviewer, OPDP*
**FDA**

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

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

*"Excellent speakers and spot-on content!"*
*–Associate Director, Marketing Operations,* **CELGENE**

*"Great speakers and topics. Sessions were highly engaging."*
*–Program Review Operations Specialist,* **GENENTECH**

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## *Dear Colleague,*

It takes intensive training to make sure all of the members of your promotional review committee — representing regulatory, medical, marketing, labeling, legal, and other divisions — have sufficient knowledge of OPDP's regulatory expectations. Even if they do, the industry's high turnover rate would mean that your PRC would still be challenged to remain in compliance with every new guideline. And as both the guidelines and your PRC composition change, it can be a constant struggle to get the entire team cooperating and meeting their deadlines.

ExL's **Promotional Review Committee Compliance & Best Practices** conference is the only industry event specifically devoted to selecting and training the best possible team members for your PRC and also making sure they can collaborate smoothly. No other event goes into as much depth on both the technical regulatory requirements and operational needs for promotional review professionals.

Now in its sixth year, our all-new agenda focuses on:

- Devising the best promotional materials for **reprints and textbooks**
- Anticipating and **preventing miscommunications with marketing agencies**
- Altering your review timeframes and processes when you must **add black box warnings**
- Standardizing the **use of references in promotional pieces**
- Translating PRC operations into **improvements in patient experience** and market strategy

Plus — because you demanded it! — this year's conference also features an in-depth, interactive workshop on **learning OPDP expectations during a sample regulatory review scenario**!

I look forward to seeing you in Morristown this fall!

Sincerely,

Matt Greenbaum

Matt Greenbaum
Production Team Leader
ExL Events, a division of Questex, LLC

## WHO SHOULD ATTEND

- Promotion Review / Promotional Review / Promotion / Promo / PRC / MPRC / PMRC
- Material Review
- Clinical Review
- Regulatory Promotion and Advertising / PromoAd / AdProm / AdPromo
- Regulatory Affairs / Regulatory Process
- Compliance / Promotion Compliance / Promotional 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

**Hyatt Regency Morristown**
3 Speedwell Avenue
Morristown, NJ 07960

To make reservations, please call 1-800-233-1234 and request the negotiated rate for **ExL's September meetings**. You may also make reservations, online at http://bit.ly/2K2WLmJ. The group rate is available until **September 4, 2018**. Please book your room early, as rooms available at this rate are limited.

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# MONDAY, SEPTEMBER 24, 2018 // WORKSHOP DAY

**1:30** Registration

**2:00** **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,** *PRO/PE Regulatory Review Officer, OPDP,* FDA
**Keren Tenenbaum,** *Assistant General Counsel,* PFIZER
**Cristina Masseria,** *Methods and Capabilities Lead,* PFIZER

**5:00** Workshop Concludes

# TUESDAY, SEPTEMBER 25, 2018 // MAIN CONFERENCE DAY ONE

**8:00** Registration and Continental Breakfast

**8:45** **Introduction From Chairperson**

## COMPLIANCE WITH NEW REGULATIONS AND MEDIA FORMATS

**9:00** **Formulate a Social Media Comment-Moderating Policy When Clear Guidance Signals Are Lacking**

Both pharma companies and patients may see no point to a social media presence that doesn't allow for reader comments, as it would be no different from a "standard" informative website. But regulatory guidelines have been ambiguous on how to handle reader comments and interactivity.

- Face the risks of turning a positive experience into a negative one
- Analyze how the industry is moving forward before enforcement penalties are known
- Learn from the enforcement history of ads on search engines

**Stephanie Jameison,** *Director, Global Regulatory Affairs, Promotion Compliance,* OTSUKA
**Heather Ramirez,** *Senior Corporate Counsel,* NOVO NORDISK
**Sabrina Mays-Diagne,** *Senior Corporate Attorney, OPDC Legal Affairs,* OTSUKA

**9:45** **Evaluate Your Transition Preparedness for the e2253 Portal**

Regulatory professionals may find the transition to e-portal submission to be a long and somewhat scary process. And while some companies have successfully made that leap, frequent team turnover can get in the way of assembling, comparing, and teaching best practices.

- Grasp the timeline of rapid advances and determine if what you already know about e2253 is obsolete
- Maintain industry expertise in spite of high personnel turnover
- Identify the service providers you can rely on for help

**Richard Lem,** *Associate Director, Regulatory Affairs, Advertising and Promotion,* BAYER

**10:30** Networking Break

**11:00** **Prepare Your PRCs to Cope With Black Box Warnings**

Even when you know from the outset that a black box warning will be on your communications, the best ways to present the remaining information are not always obvious. The need for additional fair balance may limit your comfort levels with certain types of promotions, such as digital reminder-like ads.

- Review the black box challenges of posters and banner ads
- Decide if you always must have a PI with the black box warning
- Find ways to do shorter, smaller promos that meet FDA requirements

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

**11:45** **Resolve Unanswered Questions About Using Off-Label Information**

Individual brand teams cannot be setting policy — you need a unified corporate stance on when to use off-label information in light of First Amendment court decisions. There are major new opportunities facing bold companies, but few seem to want to be the first to test limits.

- Apply differences in patient populations and sub-populations to off-label information
- Review the easing of restrictions on information for speaker programs
- Interpret court decisions and subsequent FDA actions for the finer points on what will be seen as acceptable

**Cecilia Bakker,** *Assistant General Counsel,* PFIZER

**12:30** Luncheon

**1:30** **Refine Your Promotional Review Compliance for Reprints and Textbooks**

Every reprint contains some information which may be off-label. Some companies take a very restrictive approach while choose to use reprint carriers. At the same time, some companies contribute to textbooks, and must follow specific guidelines in adding content.

- Analyze FDA guidance on distribution of scientific and medical publications
- Review approaches and disclaimers appropriate for reprints
- Modify your approach in light of best practices in handing out scientific information
- Make the best advances in positioning your company's expertise through compliant contributions to textbooks

**Alan Bergstrom,** *Commercial Regulatory Affairs,* PTC THERAPEUTICS

**2:15** **Formalize the Use of References in Promotional Pieces**

If you come across a piece where the references used have not been the right ones, it may be nobody's fault, but you still need to fix it. You may find it surprisingly challenging to ensure that the claims in a piece really reflect what the reference says.

- Devise tools for spotting mistakes early
- Correct agencies quickly on reference misuse
- Account for different experience levels among agencies

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

**3:00** Networking Break

**3:30** **Anticipate and Prevent Miscommunication With Marketing Agencies**

Your entire PRC process will benefit if you get your marketing agency properly trained and make sure they pay attention to the importance of accuracy. Share as much as you can with them before the process begins, regarding your expectations, norms, and SOPs.

- Involve multiple perspectives when communicating with agencies
- Acknowledge the frustrations that can come from sloppy work
- Prioritize the correct methods for using references

**Joyce Pearl,** *Senior Manager, Marketing Services,* MALLINCKRODT

**4:15** **Gather Perspectives and Experience When Reviewing Promotional Websites**

It may not always be clear what you can and cannot say when making comments on promotional websites, especially if your PRC members are not all at the same level of experience in your company or the field as a whole. A real-time sample review of a website can be very helpful for identifying and working through pain points.

- Clarify best practices for effective communication during the review process
- Work through critiques of sample submissions
- Build experience at working within committee settings

**Janet Gottlieb,** *Executive Director, Medical Communications,* ALLERGAN
**Jimmie Overton,** *Associate Vice President, Global Medical Scientific Information and Medical Science Library,* ALLERGAN

**5:15** Day One Concludes

**8:00** Registration and Continental Breakfast

**8:45** Chairperson's Recap of Day One

## IMPROVING PRC COOPERATION AND EFFECTIVENESS

**9:00** **Prioritize Promotional Review Agility to Increase Time for Strategy and Patient Value**

With a comprehensive, multi-pronged educational initiative, UCB aims to help content originators create submission-quality materials and reduce cycle time from rework. Education should begin upstream, before a review starts, to overcome common roadblocks such as limited review experience or incomplete knowledge of regulatory requirements.

- Ensure that contributors have the same regulatory knowledge baseline
- Remove non-negotiable, non-compliant elements from submitted copy
- Employ portals, mentorships, training, and certification to create more time to focus on brand strategy

**Jan Jeffords-Schenck,** *Assistant Director, Review Services,* UCB
**Ariail Roberts,** *Senior Manager, Review Services,* UCB
**Ilyssa Levins,** *President,* CENTER FOR COMMUNICATION COMPLIANCE

**9:45** **Evaluate the Editor Model for PRCs**

An Editorial Content Manager is much more than a proofreader for your PRC. They are involved in the earliest creative stages to help with brand partnerships, draft review, and assuring the use of the most up-to-date regulatory language.

- Guide wordsmithing to get up to review-ready high caliber
- Prescreen submissions to make sure they are review-ready and accelerate reviews per piece
- Move towards fewer revisions, resubmissions, and rejections of promo pieces

**Terri Silver,** *Senior Copy Editor, Immunology,* UCB

**10:30** Networking Break

**11:00** **Modify Your PRC Approach During Crisis Response**

If your team has hit a wall and can go no further, or unforeseen market changes require a rapid response, what is the best way to proceed? Sometimes, your best efforts at responding to one crisis will actually cause another by changing the workload of your reviewers.

- Prioritize problems and determine what gets rescheduled and pushed aside
- Clarify thresholds for escalating reviews to higher levels
- Spot the warning signs of slowdowns and avoid them as much as possible

**Denise Sanchez,** *Executive Director, Regulatory Affairs Advertising and Promotion,* ALLERGAN

**11:45** **Stay Within Proper Channels and Avoid "Offline" Reviews**

Some colleagues may not recognize that promotional review is not your only job; if that is the case, you may find yourself frequently asked to accommodate ad hoc, "offline" reviews. By setting firm boundaries, you can help make sure requests are only brought up in a proper meeting timeframe.

- Make sure marketing colleagues and agencies are properly prepared
- Aim towards giving as much notice for reviews as possible
- Cultivate a team culture of mutual respect

**Jacob Nyman,** *Director, Office of Promotion and Advertising Review,* MERCK

**12:30** Luncheon

**1:30** **Incorporate Execution Risk Into Marketing Material Review**

Promotion is more than the development of marketing materials. Mature organizations can utilize compliance program feedback to understand how marketing materials are utilized and refine promotional strategies to appropriately address risk.

- Understand how practical considerations in message delivery can impact labeling
- Include compliance in promotional tactic reviews
- Improve review processes by identifying execution risk pitfalls

**Dan Spicehandler,** *U.S. Compliance Officer,* SANOFI PASTEUR

**2:15** **Choose and Decipher Performance Metrics for PRC Software**

Some promotional review software platforms are growing much more popular than others — but are you quite certain what they mean? Even if the system is highly configurable, without clear guidelines and performance metrics, your team may struggle to get the most out of it.

- Review cross-team and cross-company expertise to see what people find to be software "success"
- Understand what you most need to get from reporting on PRC software
- Think out of the box when communicating with your software vendors

**3:00** Conference Concludes

*"Thorough explanation of the roles and responsibilities of review committees, and great insights shared on building credibility. Excellent presentations, interesting, and insightful! It was valuable for me to attend this conference."*

*—Marketing Communications Manager,* **NOVARTIS**

*"Excellent presentations and content all-around. I learned a lot!"* *—Director, Medical Affairs,* **MEDA PHARMACEUTICALS**

To Register, Call 201 871 0474 or Click Here

# 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:** 253 663 7224

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

| | |
|---|---|
| **EARLY BIRD PRICING** *Register Before Friday, August 17, 2018* | |
| Conference | $1,895 |
| Conference + Workshop | $2,195 |
| **STANDARD PRICING** | |
| Conference | $2,095 |
| Conference + Workshop | $2,395 |
| **ONSITE PRICING** | |
| Conference | $2,295 |
| Conference + Workshop | $2,595 |

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POB 2303
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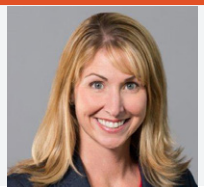

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*Assistant General Counsel*
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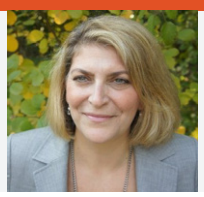

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