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

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

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

“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

For More Information, Call 866-207-6528 or Visit www.exlevents.com/prc-midwest
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.

ExLs 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 division of Questex, LLC
jcastellano@exlevents.com

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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

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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/2H0SJyI. 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 promotional items to attendees. Exl Events will work closely with you to customize a package that will suit all of your needs. To learn more about these opportunities, please contact Chris Summa at 917-932-0432 or csumma@exlevents.com.

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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 Onwudie, 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  Session Sponsored by Veeva
Bill Robinson, Director, Commercial Content Strategy, VEEVA

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

Sridhar Peddi, Manager, Advertising and Promotion, Regulatory Affairs, TAKEDA

10:30  Networking Break

11:00  PANEL: Establishing Reference Workflows to Improve Library and Asset Management
Share best practices on what system requirements should be considered when evaluating how to upload, review, and approve References
Discuss the importance of establishing ongoing monitoring and evaluation procedures to ensure up to date available data.
Ensure your reference process is optimized to handle all types of content

Moderator: Rebecca Burnett, Executive Director, Head of Strategic Services, FRAMEWORK SOLUTIONS
Jason Benagh, Manager, Marketing Operations, ALKERMES
Ann Dibiase, Director Field Training, BLUE BIRD BIO

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

For More Information, Call 866-207-6528 or Visit www.exlevents.com/prc-midwest
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, Associate Director, Regulatory Affairs, U.S. Advertising and Promotion, ABBVIE


daniel day one concludes

3:00 Networking Break
3:30 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

Heather Goldstein, Marketing Services Effectiveness Manager, TAKEDA
Robert Masi, Associate PRO Manager, GENENTECH
Christi Bruce, Senior Manager MLR Operations and Platforms, SANOFI
Kelcey Heaman, Marketing Operations Manager, ALKERMES

4:30 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
Christi 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 overcoming the dynamics and interpersonal differences and characters in each meeting and as a whole.
- Understand best practices to be efficient and objective of all parties
- Approach the commercial interest vs. medical, legal and regulatory
- Establish efficient and product approaches from a legal and compliance perspective

Jeremy Lutsky, Senior Counsel, Mannatt Phillips & Phillips, LLP
Mike Smith, Senior Counsel, PDL BIOPHARMA

12:30 Luncheon
11:45 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
Maninee Patel, Senior Manager, Regulatory Affairs, Advertising and Promotion, BAXTER HEALTHCARE

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.
- 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

3:00 Conference Concludes
**WAYS TO REGISTER**

**Phone:** 866-207-6528  
**Mail:**  
**Online:** www.exlevents.com/prc-midwest  
**Email:** registration@exlevents.com  
**Fax:** 888-221-6750

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

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<th>EARLY BIRD PRICING (Register Before Friday, March 29, 2019)</th>
<th>STANDARD PRICING</th>
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<td>Conference</td>
<td>$1,795</td>
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<td>Conference + 1 Workshop</td>
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<td>Conference + 2 Workshops</td>
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**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 866-207-6528.

- **SAVE 25%** PER PERSON WHEN REGISTERING FOUR
  For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

- **SAVE 15%** PER PERSON WHEN REGISTERING THREE
  Can only send three? You can still save 15% off of every registration.

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**TERMS AND CONDITIONS:** By registering for an ExL Events (“ExL”) event, you agree to the following set of terms and conditions listed below:

**REGISTRATION FEE:** The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

**PAYMENT:** Make checks payable to ExL Events and write 789619 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

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- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
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**CREDIT VOUCHERS:** Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of cancellation, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees’ behalf, the credit voucher will no longer be valid.

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**SUBSTITUTION CHARGES:** There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

**Fees and policies may be subject to change without notice.**

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