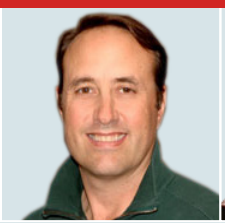
May 17-18, 2018 || Conrad Chicago || Chicago, IL

5th 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



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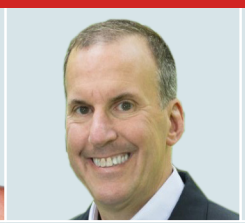
Senior Manager, Marketing Operations
ABBVIE

Sue Duvall
Head, North America Advertising and Promotion, Regulatory Affairs
MYLAN



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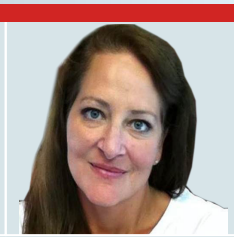

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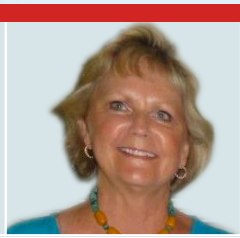
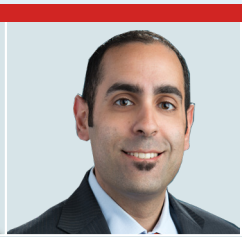
ZAVATION MEDICAL PRODUCTS



Ilze Antons
Senior Director, Advertising and Promotion, U.S. Regulatory Affairs
LUNDBECK



John Marcus
Director, Regulatory Affairs, Labeling, Advertising and Promotion
HORIZON

The guidance you need — at the leading industry event for improving PRC teamwork, speed, and regulatory compliance! Featuring all-new examinations of:

- Use of data consistent with labels
- Gradual and immediate label updates
- Risks and successes of patient support programs
- Adapting to VR and telemedicine
- Successful evaluation of convention materials
- Streamlining editorial and QC processes into promotional review
- Negotiating to avoid committee conflict
- Building a way forward when FDA enforcement is lacking

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IN-DEPTH, INTERACTIVE WORKSHOP: FDAMA 114 Promotional Review and Compliance Strategies

"Great info and interactive event. Lots of audience participation is a hallmark of a successful workshop!"
—Senior Director, Regulatory Affairs, Advertising and Promotion, **ALKERMES**

"I gained great perspective of the challenges facing my peers and how they addressed them."
—Associate Director, Promotional Regulatory Affairs, **ASTRAZENECA**

"Content was relevant for today's concerns and issues. One of the better conferences I have attended in recent years."
—Senior Manager, Marketing Services, **ABBVIE**

Dear Colleague,

Last year, FDA issued new draft guidance on promotional communications, with special emphasis on the use of data that is consistent with product labeling. While highly important, this guidance is also ambiguous in some areas — and since there have not yet been high-profile warning letters issued over violations, promotional review professionals may be struggling for lack of a clear signal on how to proceed.

ExL Events is proud to invite you to attend its **5th Promotional Review Committee Compliance & Best Practices — Midwest** conference: the only industry event devoted specifically to optimizing the skill sets, teamwork, speed, and regulatory awareness of your PRC members. No other event goes into as much detail about both the latest regulatory guidelines facing your teams and the operations and leadership techniques they require in order to succeed!

Special highlights this year include:

- In-depth examination of the use of **data consistent with labels**
- Evaluation of **promotional materials for conventions**
- New skills for compliance in **VR and telemedicine**
- Special insight on PRC responsibilities for **Patient Support Programs**
- New insights on the **quality control processes** essential for your PRC

Plus — by popular demand — this year's event features an in-depth, interactive workshop focusing on **PRC compliance with FDAMA 114**!

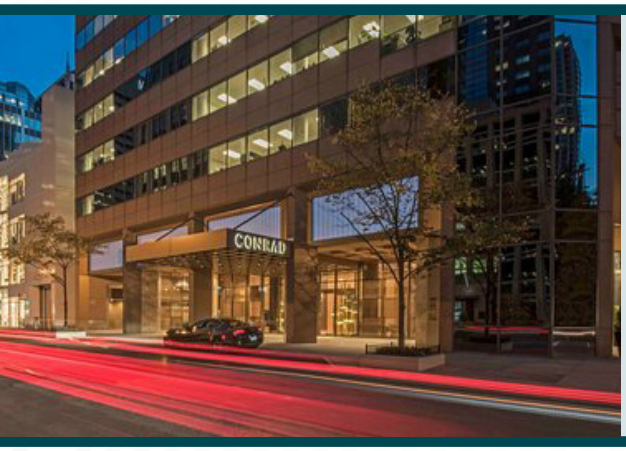
"Great discussions. I heard many different perspectives and gained insights on PRC improvement."
—Senior Manager, Promotion Compliance, **OTSUKA**

WHO SHOULD ATTEND

- Promotion Review / PRC / MPRC / PMRC
- Promotional Materials / Material Review
- Regulatory Promotion and Advertising / PromoAd / AdProm / AdPromo / Copy Editing
- Regulatory Affairs / Process
- Compliance / Promotional Compliance
- Labeling
- Health Economics / Outcomes Research / Outcomes / HEOR
- Editor / Editorial
- Medical Affairs / Review
- Medical Information
- Communications
- Medical Communications / Information / Medical Science Liaison
- Medical Writing / Scientific Writing
- Medical Director
- Marketing / Marketing Operations / Communications / 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



Conrad Chicago
101 East Erie Street
Chicago, IL 60611

To make reservations, please call 844-676-2522 and request the negotiated rate for the **ExL conference**. You may also make reservations online at **http://bit.ly/2nZHTzx**. The group rate is available until **April 25, 2018**. Please book your room early, as rooms available at this rate are limited.

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THURSDAY, MAY 17, 2018 // WORKSHOP

8:00 **Registration and Continental Breakfast**

9:00 **WORKSHOP: FDAMA 114 – Promotional Review and Compliance Strategies**

Compliance with FDAMA 114 has always been challenging. However, the long-awaited FDA Guidance has added clarity as well as raised some important questions. Typical healthcare economic information (HCEI) in promotional pieces uses methodologies that are not consistently applied. How straightforwardly do your teams communicate with payers using HCEI, and does every copy review team member understand the demands of their role?

- Review the history of the FDAMA 114 regulatory framework
- Analyze the 2017 FDA Draft Guidance
- Discuss evidentiary standards for HCEI
- Explore the scope of the intended audience for HCEI and value messages
- Clarify processes for getting reviewers trained on the HCEI evidentiary standards, methodologies, and limitations
- Bring in expertise from Legal, Medical, and Compliance colleagues

Erica Chertow, *Director, Regulatory Affairs, U.S. Prescription Drug Promotion,* **ABBVIE**
Jessica Cirillo, *Director, HEOR – Acute Care Lead,* **MALLINKCRODT**

12:00 **Lunch for Workshop Participants**

THURSDAY, MAY 17, 2018 // MAIN CONFERENCE DAY ONE

12:00 **Registration**

1:00 **Chairperson's Opening Remarks**

John Marcus, *Director, Regulatory Affairs, Labeling, Advertising and Promotion,* **HORIZON PHARMACEUTICALS**

TECHNIQUES FOR NEW REGULATIONS AND PRODUCT AREAS

1:15 **PANEL: Conduct Both Gradual and Immediate Label Updates**

Label updates often don't have specific timelines, nor are there regulations specifying how long you have to update all of your materials. How can you determine whether all promotional items need to be changed immediately? And under what circumstances can you continue to use preexisting stock until it is depleted?

- Secure input from both marketing and regulatory experts
- Install top-notch version controls and tracking
- Set company criteria for gradual and immediate updates

Sue Duvall, *Head, North America Advertising and Promotion, Regulatory Affairs,* **MYLAN**

Michael Saad, *Senior Manager, Marketing Operations,* **ABBVIE**

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

2:00 **Analyze the Promotional Compliance Risks and Successes of Patient Support Programs**

It is increasingly common for drug companies to provide copay/reimbursement assistance to patients, along with prescription drug use education to patients, nurses, and other support staff. As these grow more popular, regulators also increasingly scrutinize them. What are the most helpful future applications of these programs – and what are the compliance risks you should monitor the most?

- Review the spectrum of information sources made available through patient support programs
- Recognize when assistance programs may actually direct patients to competing products
- Draw key links and lessons for your PRC based on the needs of support programs

John Marcus, *Director, Regulatory Affairs, Labeling, Advertising and Promotion,* **HORIZON PHARMACEUTICALS**

2:45 **PANEL: 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

Steve Gersten, *Vice President, General Counsel, and Chief Ethics and Compliance Officer,* **DYNAVAX TECHNOLOGIES**

Leeann Bonaventura, *Associate Director, Promotional Regulatory Affairs,* **ASTRAZENECA**

Alexander Zachos, *Senior Manager, Regulatory Affairs, Labeling and Advertising,* **INTERCEPT PHARMACEUTICALS**

3:30 **Networking Break**

4:00 **PANEL: Evaluate the Use of Data "Consistent With Labels"**

The January 2017 regulatory guidance added a new category of data "consistent with labels": where previously you could only include on-label content, this introduces new ambiguity in publications. What exactly do these changes mean, and how are PRCs interpreting them?

- Embrace change to further the education of customers
- Outline new messaging options while avoiding noncompliance
- Track early cases of companies interpreting new guidance

Lynn Bowen, *Director, Commercial Regulatory Oversight,* **VERTEX PHARMACEUTICALS**

Jennifer Banovic, *Executive Medical Communications Liaison,* **TAKEDA**

James Vigil, *Director, U.S. Regulatory Affairs, Advertising and Promotion,* **ABBVIE**

4:45 **Telemedicine, VR, and More: Anticipate the Greatest Challenges Facing PRCs in the Next Decade**

An increasingly interconnected and virtual healthcare marketplace provides PRCs with all-new challenges. It can be very difficult to determine best practice in telemedicine and teledetailing, where there may be no in-person salesperson interaction at all.

- Explore how to give adequate disclosure over virtual meetings to in-home offices
- Understand methods for equal prominence of submissions when communicating about different types of devices
- Survey the landscape of major companies' approaches to telemedicine

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

5:30 **Day One Concludes**

FRIDAY, MAY 18, 2018 // MAIN CONFERENCE DAY TWO

8:00 Continental Breakfast

8:45 Chaiperson's Recap of Day One

John Marcus, *Director, Regulatory Affairs, Labeling, Advertising and Promotion,* **HORIZON PHARMACEUTICALS**

TOOLS FOR TEAMWORK, EFFICIENCY, AND SPEED

9:00 PANEL: Develop QC Processes for Promotional Review

Your operations team ensures 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

Mimi Giordano, *Senior Copy Editor,* **UCB BIOSCIENCE**

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

9:45 Learn the "Soft Skills" of Negotiation to Avoid Conflict Within Committees

Increasingly more pharma companies are investing their efforts in "soft skills" of negotiation, communication, and influencing authority, in order to make a more effective partnership. Each PRC stakeholder needs to know how to influence the others, but not everyone has the resources necessary to hone these skills.

- Analyze the usefulness of commercial training departments/ professionals
- Pinpoint where negotiation training would have the most impact on your operations
- Prioritize group activities so peers can fully engage

Elke Carter, *Regulatory Manager,* **ZAVATION MEDICAL PRODUCTS**

10:30 Networking Break

11:00 Analyze and Anticipate Patterns in Review Comments

What areas of consistency can you find in PRC comments, particularly within the same functional areas? Recognizing comment patterns concerning efficacy, safety, and other factors can help accelerate reviews while clarifying time management skills.

- Standardize and analyze the comments you receive
- Provide feedback to those who create materials
- Allow for crafting better promotional items by understanding comment patterns

Leeann Bonaventura, *Associate Director, Promotional Regulatory Affairs,* **ASTRAZENECA**

11:45 Ensure Compliant Presentation and Successful Evaluation of Convention Materials

As educational conferences grow more complex, pharma companies are deploying more intricate marketing and digital tools, including virtual reality. Are you prepared to meet regulatory requirements for convention panel materials?

- Prioritize what marketing and legal compliance must consider for convention materials
- Specify how much material is expected to be distributed and what units are used for each live, in-person media
- Map the types of materials and submission timelines for FDA review

Zafar Toor, *Senior Director, Commercial Regulatory Affairs,* **LEXICON PHARMACEUTICALS**

12:30 Luncheon

1:30 PANEL: Find the Optimal Timeframe for Your Review Process

Nearly all PRCs face time pressures during product launches, or when new data or competitive changes are revealed. When submitting and coordinating so many promotional items among multiple team members, how can you best address instances of critical need for speed beyond your typical process?

- Explore whether Sharepoint and other tools can help implement better crisis management skills
- Anticipate when standard processes are most likely to be disrupted and build proactive action plans
- Build a rationale for changing the standard time frame

Stacy Harker, *Manager, Promotional Compliance,* **ALLERGAN**

Megan Francis-Sedlak, *Senior Manager, Medical Affairs,* **HORIZON PHARMACEUTICALS**

2:15 Highlight the Role of PRC Coordinators to Streamline Processes

How do you position the coordinator role in your company? Under some circumstances, you could hire an administrative expert, but other companies prefer outsourced solutions instead.

- Weigh the pros and cons of insourcing or outsourcing your coordinators
- Prepare for coordinators to get a fuller view of the process than most other stakeholders
- Balance the high level of intellectual awareness and commitment with the need for administrative skills

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

3:00 Conference Concludes

"Very engaging presentations."

—PRS Leader, **JOHNSON & JOHNSON**

"Great discussions. I heard many different perspectives and gained insights on PRC improvement."

—Senior Manager, Promotion Compliance, OTSUKA

"Excellent faculty and good audience participation made this very productive."

—Global Counsel, MYLAN

Registration fees for attending ExL's 5th Promotional Review Committee Compliance & Best Practices — Midwest conference:

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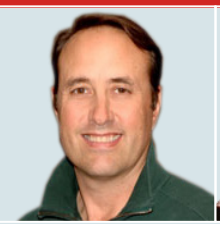

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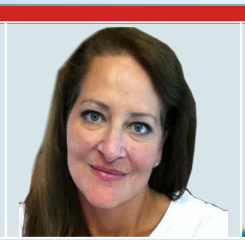

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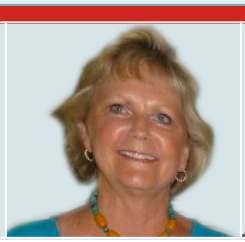

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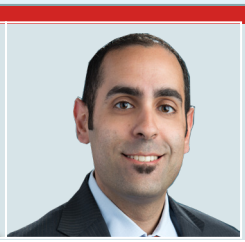

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