4TH
PROMOTIONAL REVIEW COMMITTEE COMPLIANCE & BEST PRACTICES

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

October 17-18, 2016 // The Madison Hotel // Morristown, NJ

ALL-NEW SESSIONS ON:

➜ Empowering Coordinators to Streamline PRC Operations
➜ Upgrading Submission Techniques for Adaptive Promotional Websites
➜ Confronting Compliance Challenges from Retail Pharmacy Promotions
➜ Managing a Multi-Company Review of Co-Promoted Drugs

INTERACTIVE WORKSHOP:
DEVELOP AND MAINTAIN A PROMOTIONAL CLAIMS COMPRENDIUM FOR EACH PRODUCT

A SPECIAL FOCUS ON PRC CHALLENGES FOR:

➜ Orphan Drugs ➜ Biosimilars
➜ Generic Drugs ➜ Medical Devices

"Presentations were entertaining, relevant, on-point and useful. I was very impressed with the knowledge and best practices available."
—Senior Regulatory Affairs Specialist, Ad/Promo, ABBOTT VASCULAR

YOUR CO-CHAIRS:

John Marcus
Associate Director, Regulatory Affairs
ABBVIE

Rebecca Rebmann
Senior Promotional Review Associate
UNITED THERAPEUTICS

CELGENE Analyzes Compliance Needs for Promotional Apps
Lisa Drucker
Senior Director, Regulatory Affairs
SUNOVION Plans Long-Term Budgeting for PRC Activities
Elizabeth Theophile
Director, Promotional Materials Compliance Management

PERNIX Safeguards PRC Talent After Corporate Mergers and Acquisitions
Elke Carter
Director, Regulatory Affairs

ASTRAZENECA Updates PRC Techniques for Search Engine Optimization
Yemisi Oluwatosin
Director, Promotional Regulatory Affairs

SPONSORED BY:

Deloitte, indegine, Veeva, Vodori

For More Information Call 866–207–6528 or Visit www.exlevents.com/reviewboards
DEAR COLLEAGUE,

Even the best knowledge of OPDP expectations for promotional materials will do you no good, unless you can construct and manage a promotional review committee that functions as a true team, meeting all its deadlines and adapting to the unique compliance challenges that come with specialized therapeutics and disease indications.

The 4th PRC Compliance & Best Practices conference is the only summit that focuses specifically on building and benchmarking the teamwork of your review committee. Join us in Morristown, New Jersey to ensure your PRC is prepared to generate, collect and constructively act on expert comments for your entire drug and device portfolio.

This year, our all-new speaking faculty tackles the most pressing promotional compliance topics — as chosen by YOU, our audience! These never-before-heard discussions will empower you to:

- Select and train the ideal coordinator to drive your PRC process
- Design compliant promotional messaging on apps and social networks
- Go beyond the letter of the law to protect your company’s reputation among patients for depicting their needs seriously and respectfully
- Diversify your PRC’s skill sets to meet the unique approval challenges of generic drugs, biosimilars, orphan drugs, medical devices and much more
- Maintain PRC talent and cohesion after corporate mergers and acquisitions

Plus: Return to work armed with even more information by attending our in-depth interactive workshop devoted to best practices for assembling and using a claims compendium for each product under review!

I look forward to welcoming you to the premier platform for discussing and learning about promotional review strategies this fall!

Matt Greenbaum
Production Team Leader, ExL Events
mgreenbaum@exlevents.com

VENUE
THE MADISON HOTEL
One Convent Road
Morristown, NJ 07960

To make reservations, please call 973-285-1800 or 1-800-526-0729 and request the negotiated rate for ExL’s October Meeting. The group rate is available until September 26. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND
This conference is specifically designed for pharma, biotech and med device professionals responsible for:

- Promotion Review/PRC/MPRC/PMRC
- Material Review
- Regulatory Promotion and Advertising/ PromoAd/AdProm/AdPromo/Copy Editing
- Regulatory Affairs/Processes
- Compliance/Promotional Compliance
- Labeling
- Medical Affairs/Review
- Medical Information
- Communications
- Medical Communications/Information
- Medical Science Liaisons
- Marketing/Marketing Liaisons/Communications/Services
- Commercial Operations
- Brand Management/Product Management/ 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

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Do you want to spread the word about your organization’s solutions and services to potential clients who will be 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 Eric Morrin, Senior Business Development Manager, at emorrin@exlevents.com or 212-400-6228.

“Great content. Very thorough explanation of committee roles and importance.”

—Contracts Manager, SPECTRUM PHARMA

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DEVELOP AND MAINTAIN A PROMOTIONAL CLAIMS COMPRENDIUM FOR EACH PRODUCT

It is the brand team’s responsibility to develop a core claims compendium, with input from the PRC. Challenges arise when you encounter rapid industry changes and the spread to new media formats. If a new claim does not exist in your core claims guide, what is the process under which you could use it? Additionally, the construction and word choice in a new claim can significantly impact your review process. Does abbreviating a phrase or omitting a bullet point to save space change the meaning of what is presented? If so, how should you proceed? This workshop will address how to:

- Distinguish between the perceived definitions of claims among both marketing and reviewers
- Prepare to consider even nonverbal background material as being a claim or claim-related
- Specify whether new visual aids or website elements need separate concept preapproval processes
- Conceptualize the impact of wording changes as perceived by regulatory reviewers
- Firmly instill knowledge of which terms can be modified and abbreviated and which cannot
- Overcome the challenges of modifying DTC and healthcare provider material

Rebecca Rebmann, Senior Promotional Review Associate, UNITED THERAPEUTICS
Denise Sanchez, Director, Commercial Regulatory Affairs, IRONWOOD PHARMACTICALS
Yemisi Oluwatosin, Director, Promotional Regulatory Affairs, ASTRazeneca

There will be a 30-minute networking break as part of the workshop.

IMPROVE TRAINING AND STRUCTURAL SKILLS FOR PRC MEMBERS

ONBOARD NEW TALENT AND LEVERAGE YOUR PRC PROCESS TO INCREASE QUALITY OF MATERIALS AND APPROVAL TIMES

An ideal PRC would spend less time editorializing and more time approving material assets, but a high level of turnover — particularly in marketing departments — can be an obstacle. New prioritization and management techniques can help make sure you always have materials ready for review and publication, and that your talent is producing review-ready content.

- De-prioritize other reviewer activities to add extra time to the docket
- Employ new resource modeling projects
- Avoid contract resources that don’t deliver sufficient project-based orientation or effectively manage contract resources

Ariail Roberts, Senior Manager, Review Services, UCB Pharma

CASE STUDY: IMPROVE THE EFFECTIVENESS AND EFFICIENCY OF PRCS

Anand Kiran, Executive Vice President, Global Operations, Medical Solutions, INDEGENE
Lu Ann Binda, North America Lead, Promotional Operations, PFIZER

NETWORKING BREAK

IMPROVE PRC PERFORMANCE THROUGH ONLINE REVIEW MEETINGS

If your entire PRC process is held “live,” it tends to be a bigger drain on time and resources. By prioritizing an e-review system, you can give your team more flexibility, avoid inefficiencies and better meet your shared performance goals.

- Position online review as your default method unless coordinators find some reviewer comments problematic
- Quantify the differences in number and speed of PRC meetings
- Keep lines open between the coordinator and PRC members

Rebecca Burnett, Senior Director, Marketing Services, MYLAN

CLARIFY EDUCATIONAL CONTENT AND CONTEXT AMONG MSLs

PRC individuals may also oversee review for items used by MSLs, yet each must remember that this is a separate review process with its own guidelines and goals. Guaranteeing that your MSL understands the differences between messages provided in each venue can help you avoid redundant messaging and regulatory risk.

- Clamp down on the reuse of internally reviewed material at external venues
- Create universal education guidelines and training for new MSL staff
- Expand training to accommodate new team members brought on for product launches

Deirdre Smith, Medical Information Lead, CSL Behring

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5:15  SHIF THE ESTABLISHED CONTENT MANAGEMENT PARADIGM TOWARD A HOLISTIC AND MULTICHANNEL APPROACH

In order to accommodate and better manage costs and resources across all types of marketing materials, including the increasing use of digital materials, life sciences manufacturers have to utilize enhanced and streamlined approaches in the management and review of promotional materials. Based on research and experience in helping clients enhance the timeliness and impact of these activities, this session explores three areas that can shift promotional content management to a holistic and multichannel approaches.

- Reuse content to increase efficiencies and reduce redundancies in global and regional markets
- Leverage new technology, tools, and tactics to better manage cost and resources
- Accommodate multiple communication channels and keeping their use compliant

Aditi Taylor, Principal, DELOITTE & TOUCHE LLP
Jyothi Fernandes, Senior Manager, DELOITTE & TOUCHE LLP
Bill Carter, Manager, DELOITTE & TOUCHE LLP

5:45  IMPROVE YOUR ADVANCED PLANNING AND BUDGETING FOR PRC ACTIVITIES

It is difficult for PRCs to handle high volumes of review material, you can get a better idea of just what the volume will be by working cross-functionally with regulatory, medical, legal and marketing colleagues. By planning for fiscal quarters or even years into the future, you can better integrate it with the regulatory capacity of your marketing team and assure you have the resources available to support the projected volume.

- Identify deliverables and tactics far in advance
- Work with planning experts from each participating specialty area
- Learn from other organizations that manage higher volumes

Elizabeth Theophile, Director, Promotional Materials Compliance Management, SUNOVION

6:15  COCKTAIL NETWORKING RECEPTION

6:30  For More Information Call 866–207–6528 or Visit www.exlevents.com/reviewboards

TUESDAY, OCTOBER 18, 2016 // MAIN CONFERENCE, DAY TWO

8:00  CONTINENTAL BREAKFAST

8:45  CO-CHAIRS’ RECAP OF DAY ONE

John Marcus, Associate Director, Regulatory Affairs, ABBVIE
Rebecca Rebmann, Senior Promotional Review Associate, UNITED THERAPEUTICS

9:00  ASSEMBLE THE TRAINING MANUALS THAT CAN BOOST THE EXPERTISE OF YOUR PRC

You can significantly revamp your promotional review techniques by focusing on the factors that cause reviewers to miss deadlines. If PRC member training is inconsistent, you can address this by designing detailed training manuals and e-learning modules that have a real chance of changing participant behavior.

- Properly disseminate spot-check documents
- Prevent mixed messages from multiple teams that would confuse ad agencies
- Standardize PRC processes across drugs and indications

Iris Gibbs, Associate Director, Regulatory Affairs, Advertising and Promotions, REGENERON

9:30  SIMPLIFY MULTI-COMPANY PROMOTIONAL REVIEW FOR CO-PROMOTED DRUGS

When multiple drug companies co-develop and co-market a drug, it magnifies the logistical and time-management challenges PRCs face. There are several different ways to guide a joint effort, and you must bear in mind that both companies are being judged by each others’ efforts.

- Weigh the advantages of parallel versus merged review committees
- Avoid redundant work and delays in co-promotions
- Rely on a combined team’s strengths when submitting materials for review

John Marcus, Associate Director, Regulatory Affairs, ABBVIE

10:00  CASE STUDY

Presented by VODORI

10:30  Networking Break

“This is the only conference related to management of the PRC process. Content was relevant and engaging - really drove discussions.” —Marketing Services Project Coordinator, UCB PHARMA
OPTIMIZE THE ROLE OF LEGAL IN YOUR PRC

Strong regulatory and medical reviewers are of the highest importance in promotional review; this allows legal to focus on overall initiatives from the FDA as well as any potential fraud and abuse concerns, rather than only considering one specific piece.

- Emphasize the importance of concept meetings from a legal perspective
- Focus on issues that regulatory/medical reviewers do not or cannot, i.e., IP issues, the Lanham Act, etc.
- Protect the reputation of your product and company

Marianne Slivkova, Director, Commercial Legal, ACORDA THERAPEUTICS

MAINTAIN PRC TALENT AND FLEXIBILITY AFTER CORPORATE MERGERS AND ACQUISITIONS

After an M&A of a company with its own PRC structure, you need to carefully weigh whether to incorporate or dissolve this new committee. Otherwise, materials may slip through cracks and end up in the field without proper review.

- Update risk tolerance based on the cultures of the merged companies
- Evaluate the methods and pros and cons of uniting PRCs
- Understand how improperly managed mergers can lead to OPDP letters

Elke Carter, Director, Regulatory Affairs, PERNIX THERAPEUTICS
5 Ways to Register

- www.exlevents.com/reviewboards
- registration@exlevents.com
- 886-207-6528

☐ Yes! Register me for the conference + workshop!
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Conference Code: C802

Ways to Register

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