DYNAMIC GLOBAL EVENTS

JUNE 5-6, 2024
THE INN AT PENN, A HILTON HOTEL | PHILADELPHIA, PA

4TH PRC PERFORMANCE OPTIMIZATION SUMMIT

Build Cooperative Teams that Maintain Compliance Across All Platforms and Retain Expertise Despite Changing Guidelines and Rosters

ALL-NEW COVERAGE of the most urgent and topical challenges facing Promotional Review teams!

ANTICIPATE RISKS AND BENEFITS OF AUTONOMOUS PRC TASKS

Kari Loeser
VP, Chief Compliance Officer

CYTOKINETICS

HOW FAR IS TOO FAR? DETERMINE THE BEST QA PROCEDURES AFTER AN AUDIT

Kelly Linehan
Head, Marketing Operations and Business Solutions USBU

TAKEDA

EVALUATE HOW "MODULAR" YOUR PRC CAN GO

Melissa Sadowski
Director, Promotion Compliance

OTSUKA

AIM FOR CONSISTENT COMPLIANCE IN MOBILE WEBSITE AND THIRD-PARTY APP DESIGN

Tasha Hall
Executive Medical Affairs Director

EXELIXIS

REVIEW IMMERSIVE VR EXPERIENCES

Carly Schaechter
Senior Manager, Global Regulatory Advertising & Promotion

MODERNA

OUTLINE THE NECESSARY RESPONSIBILITIES FOR BUILDING AND UPDATING A CLAIMS MATRIX

Khushbu Solanki
Legal Compliance Manager

PHARMING

RAISE PROMOTIONAL REVIEW TEAM BRAND AWARENESS THROUGHOUT YOUR COMPANY

Seema Patel
Senior Director, Regulatory Advertising & Promotion

UNITED THERAPEUTICS

Lisa Latu
Associate Project Manager, Promotional Review Board

UNITED THERAPEUTICS

Rebecca Rivera Torres
Associate Director, Regulatory Affairs, Promotional Compliance & Scientific Messaging

LUNDBECK

> **All the speakers have been good – I have pearls from each presentation!**
>
> –Director, Medical Information, ALKERMES

> **I appreciated the diversity of speakers across different functions and from different sized companies. Very helpful!**
>
> -Manager, Marketing Operations & Communications, VELOXIS

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4TH PRC PERFORMANCE OPTIMIZATION SUMMIT

Promotional review professionals must be able to function as a team, cooperatively gathering feedback from colleagues who have different backgrounds and levels of seniority, making sure all voices are heard, and clearly tracking all decisions so the whole team doesn't need to start from scratch whenever there is a roster change. These priorities are always difficult, and get even harder when turnover rates stay high, some teams meet virtually, regulatory decisions seem inconsistent, and new technologies – including AI – get incorporated into your marketing pipeline. How can you make sure your PRC has the tools and training it needs to maintain compliance and meet every deadline across every platform?

The **4th PRC Performance Optimization Summit (June 5-6, Philadelphia)** is the industry's most detailed and trusted conference for sharing the teamwork, compliance, and technological adaptation expertise that you need for success. Join us to learn and network about these and other critical challenges:

- Ensuring CFL Compliance
- Preparing for Modular Content Updates
- Shaping Review Strategies for Immersive VR Experiences, Mobile Websites, and Apps
- Incorporating AI Into PRC Operations
- Building and Updating a Claims Matrix
- Training Teammates to Function as High Performers
- Raising Company-Wide Awareness of Your PRC's "Brand"

> **I loved all the speakers and sessions. I felt a lot of ground was covered.**
>
> -Associate Director, Marketing Operations, ALEXION

> **Each and every session and speaker were useful because of the real-life experiences that were shared. It was nice to hear the reality of PRC and how it exists at different companies.**
>
> -PRC Coordinator, NEUROCRINE BIOSCIENCES

WHO ATTENDS

- Promotion Review / PRC / MPRC / PMRC
- Promotional Materials / Material Review
- Program Review
- Regulatory Promotion & Advertising / Advertising & Promotion / PromoAd / AdProm / AdPromo / Copy Editing
- PRC Coordinator
- PRC Specialist
- MLRC / MLR / JRC
- Regulatory Affairs / Process
- Compliance / Promotional Compliance
- Labeling
- Art
- Health Economics / Outcomes Research / Outcomes / HEOR
- Editor / Editorial
- Franchise
- Medical Affairs / Review
- Medical Information
- Scientific Communication
- Medical Communications / Information / Medical Science Liaison / MCR
- PR Manager
- PRM / PRM Analyst
- Medical Writing / Scientific Writing
- Medical Director
- Marketing / Marketing Operations / Communications / Services
- Commercial Operations / Commercial Services / Commercial Regulatory Affairs
- Product Manager / Product Officer / Product Review / PRO
- Brand Manager / Brand Marketing
- Legal Affairs / Counsel / Regulatory Counsel / Attorney
- Internal Operations

THIS EVENT IS ALSO OF INTEREST TO:

- Marketing agencies
- Promotional review service providers
- Regulatory service providers
- CRM and tracking software providers

REGISTER

DYNAMIC GLOBAL EVENTS

4TH PRC PERFORMANCE OPTIMIZATION SUMMIT

FEATURED SPEAKERS

Madhavi Bellamkonda
Regulatory Intelligence and Advertising & Promotion Leader

INTUITIVE SURGICAL

Allyson Chambers
Director, Regulatory Affairs, Advertising & Promotion

ALKERMES

D'andra Gill
Senior Manager, Promotion Compliance

OTSUKA

Katie Graham
Lecturer

UNIVERSITY OF COLORADO SKAGGS SCHOOL OF PHARMACY

Tasha Hall
Executive Medical Affairs Director

EXELIXIS

Larry Herring
Senior Director, Global Regulatory Affairs, Advertising & Promotion

MERZ AESTHETICS

Darshan Kulkarni
Adjunct Professor

Thomas R. Kline School of Law, **DREXEL UNIVERSITY**; Principal, **THE KULKARNI LAW FIRM**

Lisa Latu
Associate Project Manager, Promotional Review Board

UNITED THERAPEUTICS

Kelly Linehan
Head, Marketing Operations and Business Solutions USBU

TAKEDA

Kari Loeser
VP, Chief Compliance Officer

CYTOKINETICS

Ashley Long
Manager, Medical Affairs

SK LIFE SCIENCES

John Paul Marcus
Senior Director, Commercial Regulatory Affairs

TRAVERE THERAPEUTICS

Heather McFalls
Director, Promotion Compliance

OTSUKA

Seema Patel
Senior Director, Regulatory Advertising & Promotion

UNITED THERAPEUTICS

Rebecca Rivera Torres
Associate Director, Regulatory Affairs, Promotional Compliance & Scientific Messaging

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Melissa Sadowski
Director, Promotion Compliance

OTSUKA

Carly Schaechter
Senior Manager, Global Regulatory Advertising & Promotion

MODERNA

Keri Shugrue
Director, Marketing Operations

BIOGEN

Khushbu Solanki
Legal Compliance Manager

PHARMING

Kavita Vazirani
Director, Regulatory Affairs, Advertising & Promotion

ALLERGAN AESTHETICS

Gary Wieczorek
Director, Regulatory Affairs

ABBVIE

Dan Zavodnick

PHARMA GENERAL COUNSEL

DYNAMIC GLOBAL EVENTS

DAY ONE

Wednesday, June 5, 2024

8:00 AM	**Registration & Networking Breakfast**
8:45 AM	**Chairperson's Opening Remarks** **Gary Wieczorek, Director, Regulatory Affairs, ABBVIE**

Maintain Regulatory Compliance Through Uncertainty and Change

9:00 AM	**PANEL: Keep Up with Regulatory Expectations to Ensure CFL Compliance**

- Reconsider stances on CFL based on the recent FDA enforcement actions
- Understand the complaints brought in recent Novartis letter
- Review discussions about presenting qualitative vs quantitative data
- Have statisticians at the table during CFL discussions to help evaluate the data and the SASS standard

Gary Wieczorek, Director, Regulatory Affairs, **ABBVIE**
Heather McFalls, Director, Promotion Compliance, **OTSUKA**
Katie Graham, Lecturer, **UNIVERSITY OF COLORADO SKAGGS SCHOOL OF PHARMACY**

9:45 AM	**Determine How "Modular" Your PRC is Willing to Go**

Most PRCs require seeing finalized pieces before review – which is against the value proposition of modular content updates. Shortening the cycle to a more tier-based structure could work, but is your team prepared for this and can they agree on the necessary steps? Finding the best regulatory signals can indicate how a modular approach would be received.

- Grapple with challenges of 2253 submissions for modular updates
- Work towards more personalized content in the evolving landscape of digital channels
- Incentivize content re-use / adaptation through shortened downstream review cycles
- Establish submission standards to further narrow the scope of review (i.e. what has changed vs what has not)

Melissa Sadowski, Director, Promotion Compliance, **OTSUKA**

10:30 AM	**Networking Break**
11:00 AM	**How Far is Too Far? Determining the Best QA Procedures After an Audit**

An OPDP audit can leave you with a list of fixes and changes to implement – and these will have to endure for years, even when the team has a new roster. How can you pinpoint the exact level of changes required without spending more money than necessary?

- Establish layers of remedial training
- Build QA assurance into your leadership dashboards
- Focus on the messaging required to keep marketing agencies within QA standards

Kelly Linehan, Head, Marketing Operations and Business Solutions USBU, **TAKEDA**

11:45 AM	**Guard the Boundary Between Scientific Exchange and Commercial Messaging – Especially When You Have No Competitors**

If you have the only drug approved for a disease state, all of your marketing will come under greater scrutiny and you will face more risk. Even purely scientific articles mentioning the sole approved candidate may be implicitly read as describing you. What is the safest way to advance under such heightened attention?

- Properly balance both disease education and branded promotional items, with necessary safety information
- Review case studies when non-commercial messaging unavoidably mentioned your product
- Track the learning journey through reminder advertising

D'andra Gill, Senior Manager, Promotion Compliance, **OTSUKA**

12:30 PM	**Luncheon**
1:45 PM	**Strategically Track Evolving Legal Decisions that Add Uncertainty to Pharma Marketing**

The debate over off-label communication has grown more complicated due to legal discrepancies between the First and Second Circuit courts, as well as FDA's evolving standards on sharing Scientific Information on Unapproved Uses (SIUU). What are the areas of legal and ethical risk for your marketing strategies, and how does that risk change when you try more innovative methods?

- Chart what differing court findings mean for your approach to off-label speech
- Evaluate risk levels of innovative marketing strategies, such as research grants, affiliations with patient advocacy groups, and royalty agreements
- Grasp the strategic implications of changing regulatory dynamics – among not only FDA but also FTC and BBB

Darshan Kulkarni, Adjunct Professor, Thomas R. Kline School of Law, **DREXEL UNIVERSITY**; Principal, **THE KULKARNI LAW FIRM**

Adapt Review Methods for New Platforms and Technologies

2:30 PM	**Review Immersive VR Experiences**

Giving doctors at congresses a first-person look at how your products act within the bloodstream can be very compelling and valuable – but what is necessary for reviewing this medium for compliance, and how can you be sure the necessary procedures will stick around through high reviewer turnover?

- Visualize the concept reviews necessary for all team members to understand VR messaging
- Share best practice so other product teams – and perhaps other companies – don't need to do redundant work when familiarizing themselves with VR technology
- Determine the best timeframe for regularly updating and sharing guidance documents

Carly Schaechter, Senior Manager, Global Regulatory Advertising & Promotion, **MODERNA**

3:15 PM	**Networking Break**
3:45 PM	**Aim for Consistent Compliance in Mobile Website and Third-Party App Design**

Reviewing mobile website and app interfaces can be difficult and misleading, because screenshots and printouts will not fully capture the patient reading experience and are difficult to upload into your systems. Apps that are designed by outside vendors might have stylistic or organizational differences that raise new risks, or that result in a viewing window that lacks the room for all necessary safety information.

- Analyze multiple presentation options for safety info, such as static, scrolling, slide-based, and pop-up
- Predetermine the flexibility of app designers and whether your safety information will fit into their style
- Archive and convey the most representative possible snapshot of your mobile assets for review

Tasha Hall, Executive Medical Affairs Director, **EXELIXIS**

4:30 PM	**Anticipate Risks and Benefits of Autonomous PRC Tasks**

Properly deployed, AI could be used to broadly rule out some documents as requiring full review, with only those that turn out to have the predetermined code words them being elevated to an actual team member. But something as simple as meeting transcription software can introduce new risk to PRC functions. An AI-based self-typing module might start to take over other activities – including migrating to other email accounts linked to the same team calendar!

- Review outcomes of past trial runs by vendors
- Understand the unanticipated consequences of AI broadening search terms or sending emails on your behalf
- Recognize where working with variable fields can help significantly streamline your workflow

Kari Loeser, VP, Chief Compliance Officer, **CYTOKINETICS**

5:15 PM	**Structure Internal and External Concept Reviews to Keep Agencies Accountable – while Maintaining Respectful Processes**

No matter how much you train your agency or marketers, there will always be pieces that push the limits and times you must push back. It takes a delicate balance to stay open to discussion while avoiding red lines – and the longer the back-and-forth goes, the greater the risk of stress and conflict. PRC managers have to go the extra mile to maintain calmness and resolve disputes.

- Provide valid reasons for stopping bold efforts
- Make sure outside agencies know what accountability looks like
- Recognize how risk tolerance varies across different disease indications

Rebecca Rivera Torres, Associate Director, Regulatory Affairs, Promotional Compliance & Scientific Messaging, **LUNDBECK**
Kavita Vazirani, Director, Regulatory Affairs, Advertising & Promotion, **ALLERGAN AESTHETICS**

Day One Concludes

DYNAMIC GLOBAL EVENTS

DAY TWO

Thursday, June 6, 2024

8:00 AM	**Registration & Networking Breakfast**

Prioritize Efficient Teamwork Even with High Turnover and Remote / Hybrid Conditions

8:45 AM	**Chairperson's Recap of Day One** **Gary Wieczorek, Director, Regulatory Affairs, ABBVIE**
9:00 AM	**Integrate the Perspectives and Priorities of Labeling and Ad/Promo Professionals**

Many PRC leaders oversee both regulatory and labeling functions, and while they are related it is important to note their different focuses. The lessons that labeling teams learn from FDA negotiations can be directly relevant for promotional review colleagues – and vice-versa. How smoothly do your sub-teams communicate with each other?
John Paul Marcus, Senior Director, Commercial Regulatory Affairs, **TRAVERE THERAPEUTICS**

9:45 AM	**PANEL: Raise Promotional Review Team Brand Awareness Throughout Your Company**

Since PRCs can review pieces created from various teams within a company (e.g., Marketing, Training, HR, Investor Relations, Corporate Communications, etc.), it is important for other departments to know who we are, what we do, and why we do it. Our internal teams need to know we are their partners, and we will work together to ensure material created is compelling and compliant. Branding your PRC, developing on-going audience-specific training for current/new employees, and getting your PRC's name out there are essential elements in building a partnership.

- Use new team logos, business cards, and other resources to raise awareness
- Develop and roll out a training module for sales representatives and commercial-adjacent teams
- Maintain branded team presence at national sales meetings and major Marketing meetings

Seema Patel, Senior Director, Regulatory Advertising & Promotion, **UNITED THERAPEUTICS**
Lisa Latu, Associate Project Manager, Promotional Review Board, **UNITED THERAPEUTICS**
Rebecca Rivera Torres, Associate Director, Regulatory Affairs, Promotional Compliance & Scientific Messaging, **LUNDBECK**

10:30 AM	**Networking Break**
11:00 AM	**Outline the Necessary Responsibilities for Building and Updating a Claims Matrix**

A Claims Matrix can be difficult to put together and manage, but from a reviewer perspective, it represents a tremendous opportunity for saving time. The past work product of multiple marketing managers can be a good starting point for a Claims Matrix – the hard part is making sure it is up-to-date.

- Spotlight areas where this process can be less burdensome
- Reduce the need for remembering individual outcomes across multiple products and campaigns

Khushbu Solanki, Legal Compliance Manager, **PHARMING**

11:45 AM	**PANEL: When "Keeping It Simple" Is Hard: The PRC Challenges of Patient-Focused Materials**

Explanatory materials meant for patients, such as drug regimen management or clinical trial expectations, need to stick to language patients understand and not overwhelm them; but getting the essential concepts into an accessible, layman-friendly format while maintaining scientific accuracy is very hard! And how do you convey key safety data quickly to someone who is stressed by a recent bad diagnosis? It can be particularly helpful for patients to hear from other patients sharing the same burdens, and here you will encounter extra challenges related to legal compliance once the drug is actually named.

- Chart the proper review for videos that intersperse both physician and patient voices
- Recognize essential requirements in "ask your doctor about—" videos and clinical trial prep materials
- Clarify your approach for branded videos that cover collaborations between patients and healthcare providers

Larry Herring, Senior Director, Global Regulatory Affairs, Advertising & Promotion, **MERZ AESTHETICS**
Melissa Sadowski, Director, Promotion Compliance, **OTSUKA**
Dan Zavodnick, **PHARMA GENERAL COUNSEL**

12:30 PM	**Luncheon**
1:45 PM	**Prepare Coordinators for Team and Agency Training**

Coordinators can set agencies up for success by training them on what both the PRC and FDA want. Creating a relationship between the agency and the coordinator, as an additional point of contact, builds more comfort and helps maintain clarity on risk profiles.

- Internalize that each agency has multiple pharma clients with distinct risk preferences
- Build off coordinator skills at proactive guidance between different groups
- Emphasize respect for schedules

Ashley Long, Manager, Medical Affairs, **SK LIFE SCIENCES**

2:30 PM	**Encourage Project Owners and Reviewers to Function as High Performers**

By pre-emptively proposing alternative wording on their own projects, high performing owners can cut down on meeting time by as much as 75%. Recognizing this new efficiency can help uplift other team members to that level and giving a standard that they should strive to achieve.
Keri Shugrue, Director, Marketing Operations, **BIOGEN**

3:15 PM	**PANEL: Maintain Consistency in Forward Scheduling to Avoid Last-Minute Submissions**

It can be hard to maintain full trust among a PRC when not all members are in the same room; it gets even harder if submitters repeatedly bring projects that are urgent and need expedited review.
What are the best group approaches for forecasting?

- Find the messaging most effective for reaching marketers
- Steer away from behaviors that erode team trust
- Visualize how to rebuild areas that have been weakened

Larry Herring, Senior Director, Global Regulatory Affairs, Advertising & Promotion, **MERZ AESTHETICS**
Allyson Chambers, Director, Regulatory Affairs, Advertising & Promotion, **ALKERMES**
Madhavi Bellamkonda, Regulatory Intelligence and Advertising & Promotion Leader, **INTUITIVE SURGICAL**

Conference Concludes

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4TH PRC PERFORMANCE OPTIMIZATION SUMMIT

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