DYNAMIC GLOBAL EVENTS

**APRIL 29-30, 2025**
**PHILADELPHIA MARRIOTT OLD CITY | PHILADELPHIA, PA**

# 5TH PRC PERFORMANCE OPTIMIZATION SUMMIT

*The original, most detailed, most trusted gathering of Promotional Review experts with in-depth strategies on building and retaining cooperative teams that stay in compliance and under deadline across all media formats!*

## Understand the National Advertising Division: Novartis and Beyond

Melissa Brown
Attorney, National Advertising Division
**BETTER BUSINESS BUREAU**

## Emphasize the Value of Regulatory Intelligence in Promotional Regulatory Affairs

Jim Ewing
Executive Director, Promotional Regulatory Affairs
**INCYTE**

## Clarify the Amount of Review Oversight Needed for Internal-Use-Only Materials

Reetu Dandora
VP, Compliance & Regulatory Counsel
**AVEO ONCOLOGY**

## Determine Optimal Compliance Methods for New CCN Dual Modality Rules

Gary Wieczorek
Director, Regulatory Affairs
**ABBVIE**

Soyini Wilson
Associate Director, Commercial Regulatory Advisor
**BRISTOL-MYERS SQUIBB**

Adam Hussain
Senior Manager, Global Regulatory Advertising & Promotion
**MODERNA**

## Grasp the Importance of Neutrality when Managing MLR Timelines & Relationships

Manfred Fleschar
Director, Group Lead, International Advertising and Promotion, Global Regulatory Affairs
**TAKEDA**

Kari Johnson
Senior Director, Medical Information and Review
**ALKERMES**

Cherrie San Pietro
Senior Marketing Operations Coordinator
**NEUROCRINE BIOSCIENCES**

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

> A good conference in covering all aspects of PRC from process to perspectives and best practices of all cross-functional areas.
> -Director, INCYTE

DYNAMIC GLOBAL EVENTS

# 5TH PRC PERFORMANCE OPTIMIZATION SUMMIT

Promotional review committees need to stay updated on changing regulatory expectations and best practices for new technologies and platforms. And regardless of the product or message, your team must function cooperatively, listening to all voices and making the changes necessary to hit all project deadlines throughout the drug life cycle.

As the original and most trusted conference for promotional review teams, we've got you covered! The **5th PRC Performance Optimization Summit** invites you to join us in April 2025, for an all-new examination of your most pressing challenges. Featured topics include:

- Determine Optimal Compliance Methods for New CCN Dual Modality Rules
- Map the Intersection Between OPDP Research and Enforcement Actions
- Build Consistent Processes and Communications Pathways to Manage Escalations
- Arm Reviewers Against Medical Health Misinformation & Disinformation
- Grasp the Importance of Neutrality when Managing MLR Timelines and Relationships

....and many more! Come learn with the most-established community of experts as you build and train your team to stay in compliance across all formats and deadlines!

## 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

REGISTER

DYNAMIC GLOBAL EVENTS

# 5TH PRC PERFORMANCE OPTIMIZATION SUMMIT

## FEATURED SPEAKERS

Melissa Brown
Attorney, National Advertising Division

**BETTER BUSINESS BUREAU**

Christi Bruce
Content Validation Process Lead, Global Customer Engagement & Operational Content

**SANOFI**

David Corrigan
Director, MLR Products

**CANOPY LIFE SCIENCES**

Alison Croteau
Director, Review Committee Operations

**REGENERON**

Reetu Dandora
VP, Compliance & Regulatory Counsel

**AVEO ONCOLOGY**

Leah Donohue
Senior PRC Specialist

**SUPERNUS PHARMACEUTICALS**

Jim Ewing
Executive Director, Promotional Regulatory Affairs

**INCYTE**

Manfred Fleschar
Director, Group Lead, International Advertising & Promotion,Global Regulatory Affairs

**TAKEDA**

Katie Graham
Lecturer
**CHAPMAN UNIVERSITY SCHOOL OF PHARMACY**
President
**MCKOY CONSULTING**

Anthony Haddad
Senior Manager, Promotion Compliance

**OTSUKA**

Adam Hussain
Senior Manager, Global Regulatory Advertising & Promotion

**MODERNA**

Kari Johnson
Senior Director, Medical Information & Review

**ALKERMES**

Georgina Lee
Senior Director, Regulatory Affairs, Advertising & Promotion

**SAGE THERAPEUTICS**

Richard Lem
Director, International Regulatory Affairs

**ABBVIE**

Nicole Rodrigues
Brand Marketing Operations Specialist

**MALLINCKRODT**

Nadine Rupeiks
Senior Brand Marketing Specialist

**MALLINCKRODT**

Cherrie San Pietro
Senior Marketing Operations Coordinator

**NEUROCRINE BIOSCIENCES**

Christine Smith
Senior Director, Regulatory Affairs

**X4 PHARMACEUTICALS**

Kevin Stark
Global Head of Advertising, Promotion, and Labeling, Regulatory Affairs

**MALLINCKRODT**

Gary Wieczorek
Director, Regulatory Affairs

**ABBVIE**

Soyini Wilson
Associate Director, Commercial Regulatory Advisor

**BRISTOL-MYERS SQUIBB**

DYNAMIC GLOBAL EVENTS

# DAY ONE

Tuesday, April 29th, 2025

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

**8:45 AM** — **Chairperson's Opening Remarks**
Manfred Fleschar, Director, Group Lead, International Advertising & Promotion, Global Regulatory Affairs, **TAKEDA**

## REGULATORY COMPLIANCE

**9:00 AM** — **PANEL: Determine Optimal Compliance Methods for New CCN Dual Modality Rules**

OPDP has just begun enforcement on the CCN rules, with a particular focus on making sure audio content matches visible supers. Does your team have full clarity on just how closely they must match?

- Analyze whether both pieces must be identical or if repeating keywords is sufficient
- Observe whether OPDP enforcement has changed
- Grapple with the broadcast and budget implications required by longer, wordier commercials

**MODERATOR:** Gary Wieczorek, Director, Regulatory Affairs, **ABBVIE**
Soyini Wilson, Associate Director, Commercial Regulatory Advisor, **BRISTOL-MYERS SQUIBB**
Adam Hussain, Senior Manager, Global Regulatory Advertising & Promotion, **MODERNA**

**9:45 AM** — **Map the Intersection Between OPDP Research and Enforcement Actions**

How much does OPDP use specific research topics to support the thinking behind enforcement actions? Even experienced PRC teams may not realize the closeness of the two. While making sure to get medical and legal colleagues involved, it is crucial to knowledge-share what OPDP is researching and where that may be leading them.

- Recap the multiple recent studies on DTC TV ads
- Evaluate both the real level and FDA's perceived level of whether viewers understand clinical endpoints as explained by commercials
- Determine the most likely pending enforcement trends

Anthony Haddad, Senior Manager, Promotion Compliance, **OTSUKA**

**10:30 AM** — **Networking Break**

**11:00 AM** — **Emphasize the Value of Regulatory Intelligence in Promotional Regulatory Affairs**

Whether we are evaluating a recent OPDP enforcement letter or an internal proposal, it can be important to understand the regulatory landscape that surrounds us. Using a few recent OPDP letters as case studies, this session will look beyond the letter and explore environmental factors that may contribute to regulatory scrutiny of promotional communications.

- Discuss key questions to ask and facts to collect based on OPDP enforcement examples
- Identify and learn from enforcement patterns
- Explore novel promotional communication concepts

Jim Ewing, Executive Director, Promotional Regulatory Affairs, **INCYTE**

**11:45 AM** — **Understand the National Advertising Division: Novartis and Beyond**

Learn how NAD can be an effective forum to challenge potentially misleading competitor claims, take a deep dive into NAD claims analysis through a series of case studies (including Eli Lilly v. Novartis and its aftermath), and explore key issues in crafting compliant health claims.

- Analyze claims substantiation, the question of fit and the problem of overstatement
- Learn about doctor-recommended claims
- Avoid the disparagement trap

Melissa Brown, Attorney, National Advertising Division, **BETTER BUSINESS BUREAU**

**12:30 PM** — **Lunch**

## COORDINATION AND COOPERATION

**1:45 PM** — **Clarify the Amount of Review Oversight Needed for Internal-Use-Only Materials**

Do your materials for national sales meetings or training sessions need to be vetted by the full committee? And if you decide the answer is yes, will your team accept this or will you get pushback?

- Evaluate the pros and cons of formal review for internal documents
- Weigh whether there is a cutoff for inclusion in PromoMats
- Understand when prior jobs have set expectations for or against internal-use reviews

Reetu Dandora, VP, Compliance & Regulatory Counsel, **AVEO ONCOLOGY**

**2:30 PM** — **PANEL: Use Tools to Identify and Handle Difficult High-Stakes Conversations**

By properly handling personality differences, you can minimize conflicts within teams and foster a more collaborative environment. It can be worthwhile to set aside devoted resources for moderated workshops that resolve differences and prevent policy disagreements from worsening.

- Run through sample scenarios that emphasize speaking candidly without emotions or anger
- Emphasize the importance of hearing even the most broadly differing perspectives
- Acknowledge the types of attitudes and approaches that can cause roadblocks – and how to address them

Leah Donohue, Senior PRC Specialist, **SUPERNUS PHARMACEUTICALS**
Nicole Rodrigues, Brand Marketing Operations Specialist, **MALLINCKRODT**
David Corrigan, Director, MLR Products, **CANOPY LIFE SCIENCES**

**3:15 PM** — **Networking Break**

**3:45 PM** — **Build Consistent Processes and Communication Pathways to Manage Escalations**

Escalations are more unpleasant when PRCs feel they are not properly notified. Regular communication with managers and specific clarity on who gets involved at higher levels can help keep things orderly and lower apprehension.

- Put together a scenario checklist that will leave no doubt when you have reached the threshold for escalation
- Clarify the processes, timeframes, and personalities involved
- Encourage team members to keep channels open with their management

Christine Smith, Senior Director, Regulatory Affairs, **X4 PHARMACEUTICALS**
Katie Graham, Lecturer, **CHAPMAN UNIVERSITY SCHOOL OF PHARMACY**; President, **MCKOY CONSULTING**

**4:30 PM** — **Integrate AI and Automation Into Your Processes – Without Pushing Marketing Coordinators Out**

The rise of automation and AI in this space can directly impact the marketing coordinator role. What new risks and opportunities will your team face if the human element is lessened?

- Evaluate the likelihood of AI recognizing and properly handling a first-level submission
- Keep realistic expectations about where AI is likely to go in your processes
- Consider ethical and legal implications of AI-driven materials – and who owns them

Alison Croteau, Director, Review Committee Operations, **REGENERON**

**Day One Concludes**

# DAY TWO

Wednesday, April 30th, 2025

| | |
|---|---|
| 8:00 AM | **Registration & Networking Breakfast** |
| 8:45 AM | **Chairperson's Recap of Day One**<br>Manfred Fleschar, Director, Group Lead, International Advertising & Promotion, Global Regulatory Affairs, **TAKEDA** |
| 9:00 AM | **Broaden PRC Input to Evidence Generation** |

- Build the best messaging around meeting clinical endpoints
- Develop a toolkit for information releases before a product is launched, or even before it is named
- Plan to build product awareness and momentum while maintaining best practice on commenting and archiving

Kevin Stark, Global Head of Advertising, Promotion, and Labeling, Regulatory Affairs, **MALLINCKRODT**

| | |
|---|---|
| 9:45 AM | **PANEL: Grasp the Importance of Neutrality when Managing MLR Timelines and Relationships** |

To maintain an efficient system, you can't sacrifice your process too many times or else you will miss deadlines. You may naturally want to give more help to a teammate who is in need of more attention, but if you overdo this, your reviewers will run out of time. How can you stay neutral within the scope of your operational role, and not sacrifice the process itself for the sake of helping out?

- Build the soft skills necessary for appropriate time management in different relationships
- Internalize that no one gets a "pass" on your mission
- Keep the compact of your process in mind at all times

**MODERATOR:** Manfred Fleschar, Director, Group Lead, International Advertising & Promotion, Global Regulatory Affairs, **TAKEDA**
Kari Johnson, Senior Director, Medical Information and Review, **ALKERMES**
Cherrie San Pietro, Senior Marketing Operations Coordinator, **NEUROCRINE BIOSCIENCES**

| | |
|---|---|
| 10:30 AM | **Networking Break** |
| 11:00 AM | **Navigate PRC Operations through Mergers & Acquisitions** |

- Fuse the expertise of both teams on co-promotions
- Build awareness of the new methods for review escalation
- Clarify how to make decisions on higher-level bodies

Georgina Lee, Senior Director, Regulatory Affairs, Advertising & Promotion, **SAGE THERAPEUTICS**

| | |
|---|---|
| 11:45 AM | **Need for Speed, or Defiance with Compliance? Handle Demand for Rapid Approval while Maintaining Proper SOPs** |

It is easier said than done to balance the speed of rigorous approvals while maintaining compliance checks. While you always want to expedite and automate some steps, the concern is whether potential problems will be overlooked.

- Walk through the expediting procedures that work best for you
- Weigh the pros and cons of a 7-day turnaround (compared to usual 31)
- Explore options for automation on PromoMats and other tools

Christi Bruce, Content Validation Process Lead, Global Customer Engagement & Operational Content, **SANOFI**

| | |
|---|---|
| 12:30 PM | **Lunch** |
| 1:45 PM | **Refocus Hiring and Training Around Risk Communication** |

The current hiring market has flattened, but it can still be difficult to get new talent with the proper skill set. More important than long regulatory experience is whether a team member truly understands commercial partners, levers and drivers, and has good communication skills.

- Learn the indicators of when team members understand risk but not how to communicate it to the product team
- Anticipate the extra training needs when colleagues from a traditional medical background move into regulatory roles
- Recognize what does and does not work when communicating risk

Richard Lem, Director, International Regulatory Affairs, **ABBVIE**

| | |
|---|---|
| 2:30 PM | **Select the Ideal Metrics for Brand-Level Reporting** |

The more rounds your review goes through, the more the brand teams will be interested in performance metrics. While this can make them feel empowered to "call out" team members, if utilized properly it can also lead to healthy and productive competition.

- Emphasize framing the metrics in a non-hostile manner
- Be clear on the warning signs of personality clashes
- Practice isolating quality and speed issues in ways that build teams without building tension

Nadine Rupeiks, Senior Brand Marketing Specialist, **MALLINCKRODT**

**Conference Concludes**

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# 5TH PRC PERFORMANCE OPTIMIZATION SUMMIT

## IN-PERSON OR VIRTUAL ATTENDANCE

**SUPER EARLY BIRD**
$1,896
Register by February 7, 2025

**EARLY BIRD**
$2,096
Register by March 7, 2025

**STANDARD**
$2,296
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**REGISTER ON-SITE**
$2,496

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**Philadelphia Marriott Old City**
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mgreenbaum@dgeconfs.com

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