2ND PRC PERFORMANCE OPTIMIZATION SUMMIT

Gathering and Leading the Best Teams Toward the Optimal Regulatory Outcomes

ONLINE LIVESTREAM
MAY 23-25, 2022

All-new agenda featuring detailed answers for your biggest challenges in team management and regulatory compliance!

Meet Regulatory Expectations for **DIGITAL ASSET MANAGEMENT**

Lav Patel
Senior Specialist, Office of Promotion & Advertising Review
MERCK

Construct and Maintain a **CORE CLAIMS COMPENDIUM**

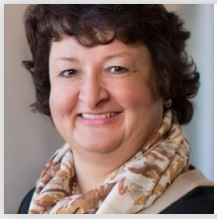
Jamie Moccia
Manager, MRC and Medical Operations
ARGENX

Rebecca Rivera Torres
Senior Manager, Regulatory Affairs
LUNDBECK

Keep Processes Running Smoothly with **ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING**

Renata Walton
Associate Director, Promotional Review Systems
JANSSEN

Innovate Review and Submission Methods for **MODULAR CONTENT**



Josephine Secnik
Director, Ad/Promo Regulatory Affairs
ELI LILLY

Monitor Compliance Risks when Working with **CELEBRITIES AND INFLUENCERS**

Larry Herring
Senior Director, Regulatory Affairs, Advertising & Promotion
MERZ AESTHETICS

Essential Compliance Strategies for New Technologies and Media:

- Telehealth
- Investor Materials
- Streaming Video
- Payer Communications
- Speaker Bureaus and Endorsements
- Real World Evidence

Committee Composition and Leadership Techniques that Bring Success in Unpredictable Times:

- Remote Launches
- Depression and Burnout
- Non-Pharma Committee Backgrounds
- Reviewer Recruitment
- Empowering Coordinators
- Small Pharma and Start-Ups

> **Good for finding out how others are doing things in the industry. Highly recommended!**
> -Head of Promotional Excellence, SANOFI

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ONLINE LIVESTREAM

2ND PRC PERFORMANCE OPTIMIZATION SUMMIT

Promotional review professionals have always faced challenges of working on collaborative team projects, getting what they need from advertising agencies, and operating on the same wavelength as subjective regulatory reviewers. COVID-19 has magnified all of those challenges and many others: teams may no longer meet in-person, the staff turnover rate is unprecedented, and the emergence of new media formats and technologies requires rapid training.

DGE's 2nd annual PRC Performance Optimization Summit is the most in-depth conference available devoted entirely to your team composition and regulatory compliance needs. Join us online May 23-25 for all-new examinations of the key topics requested by YOU – our audience! This year's agenda includes PRC strategies for modular content, artificial intelligence, celebrity endorsements, upgrading team training, empowering coordinators, and much more!

> **The topics were of value and the speakers were very knowledgeable on the topics they presented.** -Director, US Advertising & Promotion, ABBVIE

Who Should Attend

- 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
- Medical Director
- Marketing / Marketing Operations / Communications / Services
- Commercial Operations / Commercial Services / Commercial Regulatory Affairs
- 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
- Product Manager / Product Officer / Product Review / PRO
- Brand Manager / Brand Marketing
- Legal Affairs / Counsel / Regulatory Counsel / Attorney
- Internal Operations

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ONLINE LIVESTREAM

2ND PRC PERFORMANCE OPTIMIZATION SUMMIT

FEATURED SPEAKERS

Micheline Awad
Senior Director, Regulatory Affairs, Advertising, Promotion, & Labeling
TURNING POINT THERAPEUTICS

Holly Bowlin
Lead Counsel, Oncology Business Unit
TAKEDA

Christi Bruce
Head of Promotional Excellence & Standards for Advertising and Promotion
SANOFI

Shruti Gadhia
Senior Director, Head of Regulatory Affairs, Advertising and Promotion Compliance
KYOWA KIRIN

Janet Gottlieb
Executive Director, Medical Compliance Excellence, Medical Review
ABBVIE

Anthony Haddad
Manager, Promotional Compliance
OTSUKA

Larry Herring
Senior Director, Regulatory Affairs, Advertising & Promotion
MERZ AESTHETICS

Nancy Knickerbocker
Director, US RA Advertising & Promotion
ABBVIE

Mary Kuskin
Director, Regulatory Affairs, Advertising & Promotion
MIRATI THERAPEUTICS

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

John Paul Marcus
Regulatory Affairs, Labeling, Advertising, and Promotion
HORIZON THERAPEUTICS

Jamie Moccia
Manager, MRC and Medical Operations
ARGENX

Doreen Morgan
VP, Head of Global Regulatory Strategy
PTC THERAPEUTICS

Lav Patel
Senior Specialist, Office of Promotion & Advertising Review
MERCK

Linda Pollitz
Executive Director, Regulatory Affairs, Advertising & Promotion
ALKERMES

Ana Rasack
Promotional Advertising Lead
COOPER SURGICAL

Phil Reveal
Director, US AdPromo and Labeling
ALKERMES

Rebecca Rivera Torres
Senior Manager, Regulatory Affairs
LUNDBECK

Josephine Secnik
Director, Ad/Promo Regulatory Affairs
ELI LILLY

Keri Shugrue
Associate Director, Marketing Operations
SOBI

Kevin Stark
Executive Director, Advertising Promotional Review
ORGANON

Olivia Walker
Associate Director, Advertising & Promotion, Regulatory Affairs
BAYER

Renata Walton
Associate Director, Promotional Review Systems
JANSSEN

Gary Wieczorek
Director, Regulatory Affairs
ABBVIE

Dan Zavodnick
VP, Legal
ARCH ONCOLOGY

DYNAMIC GLOBAL EVENTS

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DAY ONE

Monday, May 23rd, 2022

ALL TIMES ARE IN EST

8:00 AM	Registration & Log In
8:45 AM	Chairperson's Opening Remarks Nancy Knickerbocker, Director, US RA Advertising & Promotion, **ABBVIE**

PRC Best Practice for New Technologies and Platforms

9:00 AM — Blaze a Clear and Consistent Regulatory Trail for Digital Asset Management

There were only 3 FDA action letters in 2021, and without that clear guidance it can be much harder to learn how to advance. It is important for organizations to not only understand current enforcement but also the trends in these enforcement actions to gauge FDA's current thinking.

- Clarify existing FDA requirements for digital assets
- Review FDA enforcement trends in the digital space
- Provide considerations for evaluating digital materials

Lav Patel, Senior Specialist, Office of Promotion & Advertising Review, **MERCK**

9:45 AM — Envision Changes to Promotional Review Techniques and Priorities for Telemedicine

Telemedicine was an expanding sector with much promise to improve patient access and outcomes even before COVID - but the regularoty oversight regime on telemedicne providers is different from that facing biopharma companies. Grasping the changes in regulatory requirements is the first step to improving your outreach.

- Gauge the frequency of off-label promotional messaging by telehealth companies
- Contrast the regulatory requirements of the pharma and telehealth companies where they may intersect with PRC work product
- Anticipate the likelihood of regulatory change

Anthony Haddad, Manager, Promotional Compliance, **OTSUKA**

10:30 AM	**Break**

10:45 AM — When New Technology Meets Old Regulations: Maintaining Compliance When Reviewing Streaming Media and Online Video

Maintaining proper balance for new streaming video formats can be surprisingly challenging, as it is governed by older FDA guidances for broadcasts that don't fully capture the user experience. What elements should regulatory reviewers consider when reviewing streaming media and online video assets?

- Understand the ways "television" has evolved and how the online viewing experience may impact regulatory elements, such as adequate provision of the prescribing information and safety balance
- Envision whether differences across platforms, such as timing limitations, interactivity, and player size will add new areas of risk
- Feel out a common sense application for guidelines that may be decades behind the technologies you are using

Olivia Walker, Associate Director, Advertising & Promotion, Regulatory Affairs, **TG THERAPEUTICS**

Shruti Gadhia, Senior Director, Head of Regulatory Affairs, Advertising and Promotion Compliance, **KYOWA KIRIN**

11:30 AM — Establish the Needed Guardrails for Compliant Review of Payer Communications

On paper it may seem basic to separate communications meant for HCPs, payers, and investors - but between the high focus on CFL and the overall stress the working world has faced during COVID conditios, some companies are still struggling with differentiating between these audiences. Though different types of data are needed for the 3 audience groups, in all cases the standard must remain that communications are truthful and non-misleading.

- Compare and contrast data standards for HCPs, payers, and investors
- Track recent enforcement actions from FDA related to CFL communications
- Learn to respond to colleagues who want to use payer data as clinical data and viceversa

Kevin Stark, Executive Director, Advertising Promotional Review, **ORGANON**

12:15 PM	**Lunch**

12:45 PM — Improve Automation with Artificial Intelligence and Machine Learning for Smoother Processes

If properly merged with your asset management format, AI tools can yield more information to your PRC and allow it to complete reviews more quickly. Particularly for label updates, there is a real need, met by an increasing number of vendors, for a tool that will quickly identify and update every location in a promotion where a claim is used.

- Outline the circumstances where an automated tool would be the most useful
- Drive AI uptake through worldwide promotions
- Compare and contrast multiple available services and tools

Renata Walton, Associate Director, Promotional Review Systems, **JANSSEN**

Maintaining Regulatory Compliance

1:30 PM — Maintain Oversight of Investor Materials

Some of your colleagues may believe that Investor Materials provided in the public domain can be used carte blanche for other purposes – and that can get you into trouble, not only with OPDP but with DOJ as well. Press releases and forward-looking statements made to investor groups must be reviewed with a different eye, and managed thoughtfully when applied for other purposes such as promotional messages and speaker decks – particularly if your product isn't approved yet.

- Internalize FDA statements as a deterrent to overeager team members
- Maintain clarity about the different levels of risks facing smaller biotech companies- move this to the first bullet point
- Invite feedback from legal colleagues

Doreen Morgan, VP, Head of Global Regulatory Strategy, **PTC THERAPEUTICS**

2:15 PM	**Break**

2:30 PM — Focus on Appropriate Communications in Media and Press Materials

Releases to the press may result in a very open forum that lacks the necessary context – and the FDA still sees this, and may take action. Every press release has to be evaluated through a PRC lens to make sure product uses are appropriately communicated.

- Remain cautious and avoid overstating data in any way
- Map out the possible impact of press releases on draft labeling and supplemental NDAs
- Budget in the necessary time for review of media materials

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

Day 1 Concludes

DAY TWO

Tuesday, May 24th, 2022

ALL TIMES ARE IN EST

8:00 AM Registration & Log In

8:45 AM Chairperson's Recap of Day One
Nancy Knickerbocker, Director, US RA Advertising & Promotion, **ABBVIE**

9:00 AM **Past Is Prologue: Reconstruct OPDP Themes to Determine Safe Paths Without Enforcement Signals**

Even though OPDP hasn't recently provided clear guidance or much public enforcement, you can still sift through past data to gain better insight on their preferences and trigger points. By looking back through letters from earlier years – no matter how rare – you may be able to identify regular themes, anticipate what future enforcement would look like, and help your teams to create impactful and compliant messages.

- Focus on the consistent characteristics and themes of enforcement letters
- Rely on advisory comment to strengthen otherwise unclear enforcement patterns
- Spot the warning signs and construct appropriate responses for of colleagues who want to "roll the dice" that OPDP may remain inactive through a particularly daring campaign

Linda Pollitz, Executive Director, Regulatory Affairs, Advertising & Promotion, **ALKERMES**

9:45 AM **Construct and Maintain a Core Claims Compendium to Harmonize All Promotional Pieces and References**

If you learn that OPDP is scrutinizing a particular claim that you have used multiple times, going back and fixing every single use will be highly time-consuming. By building and normalizing the use of a core Claims Compendium, you can allow all cross-disciplinary team members to always point to the right reference and supportive evidence.

- Gather the most important messages from your PI and supportive literature
- Set up your marketing agencies for success in producing materials that aren't repetitive
- Ensure medical affairs and commercial field teams align on messaging

Jamie Moccia, Manager, MRC and Medical Operations, **ARGENX**
Rebecca Rivera Torres, Senior Manager, Regulatory Affairs, **LUNDBECK**

10:30 AM **Break**

10:45 AM **Innovate Review and Submission Methods for Modular Content**

External stakeholders typically receive communications digitally and not in person, so do you have the best processes for handling modular updates to material rather than wholesale replacements? Best practice for modular submissions to FDA have not yet been determined, which leads to uncertainty among an industry that knows it will have to rely on them sooner or later.

- Prevent the development of an unbalanced appearance in FDA submissions
- Anticipate the needs of digital stakeholders
- Share example of module content submissions of emails and banner ads

Josephine Secnik, Director, Ad/Promo Regulatory Affairs, **ELI LILLY**

11:30 AM **Normalize Regular Proactive Legal Education for Your Entire Team**

Your legal team must be a front-and-center business partner that can advise on any potential speedbumps. Legal partners may be able to bring a big-picture view of the entire organization to the benefit of commercial and marketing colleagues when informing their new tactics.

- Maintain clarity among team members on why changes have happened from a legal perspective
- Stay ahead of notices going to marketing teams
- Acknowledge the differing legal needs of large and small pharma

Holly Bowlin, Lead Counsel, Oncology Business Unit, **TAKEDA**

12:15 PM **Lunch**

12:45 PM **Grapple with Fraud Alerts when Dealing with Speaker Bureaus and Endorsements**

PRC slide decks and other materials for speaker bureaus, endorsements, and testimonials are now under deeper scrutiny due to OIG's special fraud alert. Cross-disciplinary teams are at risk of not operating on the same baseline of knowledge of government expectations, making reviews difficult and slow.

- Emphasize the OIG's understanding of "similar topics" – which may be very different from that of your team members
- Provide examples of good and bad use of endorsements and testimonials
- Split up educational needs between legal and regulatory teams as needed

1:30 PM **When Feds Keep Up With the Kardashians: Structure Contracts and Monitor Compliance Risks when Working with Celebrities and Influencers**

Celebrity campaigns have been an area of enforcement for FDA, so you must make sure that if an influencer is promoting you on their bespoke channel, they are working within a contract that keeps them informed of how safety disclaimers should look – and keeps you out of trouble. Though they can be very helpful, celebrity activist campaigns are also time-intensive since they often require approval after every round of PRC comments.

- Look for an influencer hypertargeted for your audience
- Account for the risks of such high-profile, mass interest communications
- Split off your more aggressive messaging into parallel campaigns that will get less press

Larry Herring, Senior Director, Regulatory Affairs, Advertising & Promotion, **MERZ AESTHETICS**

2:15 PM **Break**

2:30 PM **Clarify the Use of Real-World Evidence Within the Scope of Pharma's First Amendment Rights**

Given recent FDA guidances on submissions and label broadening, are you using real-world evidence correctly in your promotions – even if it doesn't go in your label at all? It can be a market advantage to bring real-world evidence into your promotions, but this must prioritize remaining Consistent With Label.

- Understand different applications for Data Consistent With Labels
- Determine proper methods for bringing RWE into promotions
- Gain clarity on Data Consistent with Labels

Phil Reveal, Director, AdPromo and Labeling, **ALKERMES**

Day 2 Concludes

DAY THREE

Wednesday, May 25th, 2022

ALL TIMES ARE IN EST

8:00 AM Registration & Log In

8:45 AM Chairperson's Recap of Day Two
Nancy Knickerbocker, Director, US RA Advertising & Promotion, **ABBVIE**

Best Practice in Team Management and Communication

9:00 AM **Rebuild Team Cooperation for Launches under Remote Conditions**

PRC members from different verticals, such as commercial and regulatory, may not have ever worked near each other and instead only came together for meetings. Planning for a launch under these conditions can be highly stressful, and the burden falls not on sponsors or reviewers but on those who run PRC logistical operations.

- Account for changing relationships between sponsors, reviewers, and coordinators
- Take inspiration from successful team-based activities and touchpoints even when members don't meet in-person
- Acknowledge areas where teamwork has suffered, so you can counteract this

Christi Bruce, Head of Promotional Excellence & Standards for Advertising and Promotion, **SANOFI**

9:45 AM **Confront Depression and Burnout Among Team Members**

The recent years of stress and upheaval have hit your team members – hard. Even if they and their families haven't been directly touched by COVID, concern over bad news and altered working conditions can change their perceptions and ability to fulfill their tasks. PRC managers need to confront this head-on in a sensitive manner while also making sure deadlines don't slip away.

- Analyze how newly lean operations can put a single reviewer on multiple brands
- Explore methods for keeping team dynamics healthy

Janet Gottlieb, Executive Director, Medical Compliance Excellence, Medical Review, **ABBVIE**

10:30 AM **Break**

10:45 AM **Redesign Onboarding and Training to Compensate for Colleagues from Very Different Backgrounds**

With so much career mobility within the pharma sector, you can end up on a PRC with teammates who have had very different training processes in the past. Someone who might have relied on an admin will face a steeper learning curve.

- Resist assumptions about familiarity levels with tracking software
- Clearly convey expectations of balance
- Set aside the number of hours necessary to set new team members up for success

Ana Rasack, Promotional Advertising Lead, **COOPER SURGICAL**

11:30 AM **PANEL: Empower Coordinators to Save Time by Assessing Submissions for Readiness for Review**

How much authority do coordinators have within your process, and how much backup do they get from leadership? If they are put into a position where it is easier to just push through an imperfect piece and let reviewers "fix" it, the process will take longer, can lead to resentment and reinforce bad behavior.

- Ensure coordinators can recognize problems with references, annotations, and metadata
- Build trust and respect among reviewers/proponents so that urgent, business-critical turnaround may still be accomplished
- Avoid circumstances where incomplete or unacceptable materials cause misalignment between proponent and reviewers late in the process

Keri Shugrue, Associate Director, Marketing Operations, **SOBI**
Gary Wieczorek, Director, Regulatory Affairs, U.S. Advertising & Promotion, **ABBVIE**

12:15 PM **Lunch**

12:45 PM **Build PRC Processes for Start-Ups**

If a new company doesn't have the needed headcount, they can hire vendors for coordinator services – but will still need a back-end connection between operational aspects and the launch readiness team. Do you have the strong link that you need to translate tactical plans and materials into your launch plan?

- Envision the approval workflow for new processes
- Determine how best to get resources through a new system and into reviewer tablets
- Prioritize getting materials through the system without snags

Mary Kuskin, Director, Regulatory Affairs, Advertising & Promotion, **MIRATI THERAPEUTICS**

1:30 PM **Guide Big Pharma PRC Hires into the New Culture of Small Pharma**

PRC colleagues originally from large biopharma companies may be less familiar with behind-the-scenes operations that are now the norm for PRC members. Failing to set the proper expectations puts you at risk of having to write copy during review meetings for pieces that weren't completely ready.

- Educate team members about the different levels of risk and regulatory oversight facing large and small companies
- Anticipate circumstances where smaller companies may be able to "fly under the radar"
- Train new hires on direct involvement in tactical operations that they may have delegated to others at prior jobs

John Paul Marcus, Director, Regulatory Affairs, Labeling, Advertising, and Promotion, **HORIZON THERAPEUTICS**
Micheline Awad, Senior Director, Regulatory Affairs, Advertising, Promotion, & Labeling, **TURNING POINT THERAPEUTICS**

2:15 PM **Break**

2:30 PM **PANEL: Minimize Confrontations by Building a Team Culture of Respect and Open Communication**

Many PRCs struggle with a confrontational culture. This can be managed by making sure each sector understands the value of the other; but such understanding can be tough to communicate, especially when you are doing multiple reviews in sequence. You need to proactively take the time to set up the right culture for your committee.

- Make sure all reviewers see themselves as advisors and contributors rather than internal regulators
- Bring team members' attention to "default" behaviors that may need updating
- Clearly communicate expectations for teamwork and dialogue to all new reviewers

Dan Zavodnick, VP, Legal, **ARCH ONCOLOGY**
Nancy Knickerbocker, Director, US RA Advertising & Promotion, **ABBVIE**
Renata Walton, Associate Director, Promotional Review Department, **JANSSEN**

Conference Concludes

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2ND PRC PERFORMANCE OPTIMIZATION SUMMIT

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April 29, 2022

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