

 Bethesda North Marriott Hotel and Conference Center

Feb 23, 2026 7:00 AM - Feb 24, 2026 3:00 PM

5701 Marinelli Road, North Bethesda, MD 20852

# Advertising and Promotion Regulatory Affairs Conference


Advancing Advertising and Promotion in the Age of Innovation

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## Print Agenda

Day 1 Feb 23, 2026

7:15 AM — 8:00 AM

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## Networking Breakfast

7:30 AM — 5:25 PM

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# Meeting Registration

8:00 AM — 8:15 AM

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## Welcome and Opening Remarks

8:15 AM — 9:00 AM

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## Session 1: Inside the Agencies: A Fireside Chat on Promotion, Compliance, and Consumer Protection

This interactive fireside chat brings together leaders from various agencies to share perspectives on the evolving regulatory and enforcement landscape for prescription drug promotion and advertising. Panelists will discuss key areas of interagency collaboration, current enforcement priorities, and the implications for industry practices in promotion, compliance, and consumer protection. The conversation will explore how each agency approaches advertising review, substantiation standards, and risk mitigation in an increasingly complex environment. Attendees will gain practical insights to anticipate enforcement trends and strengthen their internal compliance and review frameworks.

Learning Objective :

- Identify three emerging regulatory or enforcement priorities discussed by various agencies, and summarize their impact on prescription drug advertising and promotion practices
- Compare the differing approaches and areas of overlap among the four agencies
- Evaluate how interagency coordination influences enforcement outcomes and apply this understanding to refine risk assessment and escalation processes within attendees' organizations

### Session Chair(s)



#### Twyla Mosey, PharmD, RPh

Division Director  
FDA, United States

Twyla Mosey is the Division Director of the Division of Advertising and Promotion Review II in the Office of Prescription Drug Promotion at the Food and Drug Administration. She supports the mission of protecting the public health by overseeing Division correspondences and is responsible for critical decision-making, strategic planning and all Division activities. Over the past 15 years, Twyla has held various roles within the Agency and pharmaceutical industry. She received her Doctor of Pharmacy degree from Florida Agricultural and Mechanical University College of Pharmacy and Pharmaceutical Sciences.

#### Micheline Awad, MBA

Sr. Director, Regulatory Advertising, Promotion, and Labeling  
Day One Biopharmaceuticals, United States



Micheline leads the Advertising & Promotion and Labeling functions at Day One Biopharmaceuticals. Her experience includes Regulatory Affairs Strategy, Advertising & Promotion, and Labeling for Biologics, Drugs, and Devices. Her expertise in product launches is driven by strategic planning, risk assessment, and maintaining regulatory compliance while fostering innovation and growth. She is passionate about collaborating with cross-functional partners to drive successful product launches while ensuring adherence to complex regulations and guidances. She received her MBA from University of Southern California with a focus on Strategy and Marketing, and her BS in Biology specializing in Biotechnology from George Mason University.

9:05 AM — 10:05 AM

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## Session 2: Staying Ahead of the Curve: FDA OPDP Insights to Strengthen Promotional Compliance

Gain firsthand insights from the FDA's Office of Prescription Drug Promotion (OPDP) on emerging trends, enforcement priorities, and best practices shaping the future of compliant drug and biologic advertising and promotion.

### Session Chair(s)



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Division Director  
FDA, United States

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10:05 AM — 10:50 AM

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## Refreshments, Exhibits, and Networking Break

10:50 AM — 12:05 PM

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## Session 3: DTC Promotion at a Crossroads: The Evolving Landscape of Regulatory and Legal Policy

This session will explore the shifting legal and regulatory landscape shaping prescription drug promotion in today's highly scrutinized environment. Experts will discuss the impacts of government priorities, evolving DOJ expectations, and recent changes in the OPDP/APLB advisory process for DTC advertising. Attendees will gain practical insights into how these developments are redefining risk, compliance, and strategy across the promotional review space.

Learning Objective :

- Identify legal or regulatory developments influencing prescription drug promotion and explain their implications for promotional review practices
- Evaluate how government enforcement trends and policy changes affect DTC advertising, risk assessment, and claim substantiation strategies
- Apply insights to update or refine internal promotional review or monitoring process demonstrating measurable improvement in efficiency and regulatory alignment

## Session Chair(s)



### Micheline Awad, MBA

Sr. Director, Regulatory Advertising, Promotion, and Labeling  
Day One Biopharmaceuticals, United States

Micheline leads the Advertising & Promotion and Labeling functions at Day One Biopharmaceuticals. Her experience includes Regulatory Affairs Strategy, Advertising & Promotion, and Labeling for Biologics, Drugs, and Devices. Her expertise in product launches is driven by strategic planning, risk assessment, and maintaining regulatory compliance while fostering innovation and growth. She is passionate about collaborating with cross-functional partners to drive successful product launches while ensuring adherence to complex regulations and guidances. She received her MBA from University of Southern California with a focus on Strategy and Marketing, and her BS in Biology specializing in Biotechnology from George Mason University.



### Virginia Foley

Founder, CEO  
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.

## Speaker(s)



### Speaker

### Heather Banuelos, JD

Counsel  
King & Spalding LLP, United States

Heather Bañuelos is Counsel in King & Spalding's FDA & Life Sciences practice group. She advises clients on regulatory strategies and initiatives for the labeling, promotion, and advertising of FDA-regulated products, as well as non-promotional communications, with particular focus on prescription drugs. She routinely serves on promotional review committees and medical/scientific review committees, providing practical and

insightful advice and recommendations. Heather has over 25 years of experience in food and drug law, including as a former Associate Chief Counsel in FDA's Office of the Chief Counsel and as senior in-house regulatory counsel for Fortune 500 pharmaceutical companies.



## Speaker

### Alexander Gaffney, MS, RAC

Vice President, Regulatory Policy And Intelligence  
AgencyIQ by POLITICO, United States

Alexander Gaffney is the Executive Director of Regulatory Policy and Intelligence for POLITICO's AgencyIQ, where he leads a team of more than a dozen regulatory intelligence professionals. Alexander has worked in regulatory for more than a decade, including at the Regulatory Affairs Professionals Society (RAPS) and PricewaterhouseCoopers (PwC). At AgencyIQ, his research, insights and analysis is relied upon by the regulatory teams of many of the world's leading companies. He is also the author of AgencyIQ's flagship daily newsletter, "FDA Today."

12:05 PM — 1:05 PM

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## Luncheon, Exhibits, and Networking Break

1:05 PM — 2:20 PM

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## Session 4: Innovation Meets Oversight: AI's Role in Content Creation and Promotional Review

As artificial intelligence continues to evolve and rapidly expands, regulatory reviewers require new tools to evaluate AI technologies to identify regulatory compliance risks. The session will explore the benefits and risks of using generative AI for prescription drug marketing and how marketers can implement guardrails to protect HCP and consumer perceptions of their products, ensure user privacy, and configure generative AI systems to prevent non-compliant presentations of medical information. In addition, the panel will discuss the common regulatory risks presented by AI models including training bias, application of knowledge concepts, and personas. The panel will propose a structured methodology for regulatory reviewers to assess regulatory compliance risks and appropriateness of a given AI model or solution for prescription drug marketing.

Learning Objective :

- Identify the major challenges and risks presented by Artificial Intelligence in advertising and promotion
- Discuss strategies to mitigate risks to presented by AI model hallucinations and bias
- Evaluate new tools to determine if AI models are fit for purpose
- Identify solutions and mitigation strategies to apply guardrails to real-time generative technologies

Session Chair(s)



## Nicol George, PharmD, RPh

Executive Vice President, Promotional Review & Labeling Services  
ProPharma Group, United States

Nicol George, Pharm.D., R.Ph., is the Vice President, Promotional Review Services & Labeling at OneSource Regulatory (OSR) a ProPharma Group Company, where she manages the Regulatory & Medical Review staff, provides executive level consulting services including leadership mentoring, process improvements, electronic review system implementations & Advertising and Promotion Training. Before joining OSR, Nicol was at Baxter Healthcare where she held the position of Director, Global Regulatory Affairs Labeling, Advertising & Promotion & led an international team for 5 years (2012-2017). Nicol has been in the industry for over 20 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.



## Virginia Foley

Founder, CEO  
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.

### Speaker(s)



## Regulatory Review in the age of AI

### Jason Cober, MPA

Director Regulatory Review, AI, Digital Transformation  
ProPharma Group, United States

Jason Cober is the Director - Regulatory Review, AI, and Digital Transformation at ProPharma Group. He previously led FDA/OPDP's eCTD implementation and has 17 years' experience with the Agency's eCTD specification and guidance development process.

2:20 PM — 3:05 PM

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## Refreshments, Exhibits, and Networking Break

3:05 PM — 4:20 PM

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# Session 5: Emerging Trends for Leveraging Patient Reported Outcomes (PROs) Inclusion in Labeling and CFL Communications

This session will provide a case study of an Exploratory PRO Inclusion in Oncology Labeling as well as discussion on leveraging CFL to communicate on PROs that may not be in labeling but are consistent with labeling. Finally, we will review recent enforcement relating to PRO promotion.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Identify emerging trends in the inclusion of Patient Reported Outcomes (PROs) in product labeling and corresponding CFL communications
- Discuss strategies for communicating PROs in CFL materials that align with labeling, and review recent enforcement actions related to PRO promotion

## Session Chair(s)



Heta Zaveri, PharmD, MBA

Ad Promo Account Executive  
Opus Regulatory Inc, United States

## Speaker(s)



FDA's Proactive Inclusion of PRO-CTCAE, an Exploratory Measure, in an Oncology Drug Label, Risk or Opportunity for Industry?

Denise Sanchez, JD, MA, MS

Principal Consultant  
Opus Regulatory Inc., United States

Denise has worked in the regulatory space for 20 years with combined industry, government and law firm experience. Industry roles include Regulatory overview of commercial promotion and practices at Allergan Aesthetics, Ironwood, Celgene, & Cubist. At the law firm Hughes, Hubbard, and Reed, Denise worked on drug off-label promotion & product liability litigation. Denise's federal government tenure focused in the public health service, as Regulatory Counsel for CDRH and CBER, FDA and congressional policy at the National Cancer Institute, NIH. Denise completed undergraduate & public health graduate study at Columbia University, biomedical sciences graduate work at Rutgers, & law study at Georgetown University Law Center.

## Speaker

Nada A. Glavan, MPH

Executive Director, Commercial Regulatory Affairs





Eisai US, United States

Nada Glavan is an accomplished regulatory affairs leader with more than 25 years of experience guiding pharmaceutical companies through the complexities of advertising and promotion compliance. Throughout her career, Nada has built a reputation for her ability to bridge the gap between scientific innovation and regulatory requirements, partnering with cross-functional teams to support product launches, lifecycle management, and commercial success. She currently serves

as Executive Director, Commercial Regulatory Affairs at Eisai Inc.



Speake

Representative Invited

AbbVie, United States

4:30 PM — 5:30 PM

## Session 6: SIUU Who? Best Practices and Limitations

This session will examine the evolution of the FDA's Good Reprint Practice guidances leading up to the finalized 2025 Scientific Information on Unapproved Uses (SIUU) guidance, highlighting both new elements and limitations. Attendees will learn about materials that qualify or do not qualify for dissemination under SIUU and the critical role of the regulatory reviewer in the approval and dissemination processes. An interactive component will allow participants to evaluate SIUU scenarios to reinforce their understanding of the guidance and discuss practical and compliant execution.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Assess what types of materials qualify for dissemination under SIUU guidance
- Illustrate the promotional review team's role in review, approval and execution of SIUU dissemination
- Identify regulatory expectations and practical considerations for compliant communication of scientific information on unapproved uses

### Session Chair(s)



Alyson Andrikanich, PharmD

Senior Director, Advertising and Promotion, Regulatory Affairs Americas  
Bayer Pharmaceuticals, United States

Alyson Andrikanich is a Senior Director in Regulatory Advertising and Promotion at Bayer Pharmaceuticals. She has over 15 years experience in the pharmaceutical industry, specializing in advertising and promotion in regulatory affairs. Alyson completed a post-doctoral industry

fellowship program through Rutgers University and Bayer in Medical Communications/Medical Affairs.

Nicol George, PharmD, RPh

Executive Vice President, Promotional Review & Labeling Services  
ProPharma Group, United States





Nicol George, Pharm.D., R.Ph., is the Vice President, Promotional Review Services & Labeling at OneSource Regulatory (OSR) a ProPharma Group Company, where she manages the Regulatory & Medical Review staff, provides executive level consulting services including leadership mentoring, process improvements, electronic review system implementations & Advertising and Promotion Training. Before joining OSR, Nicol was at Baxter Healthcare where she held the position of Director, Global Regulatory Affairs Labeling, Advertising & Promotion & led an international team for 5 years (2012-2017). Nicol has been in the industry for over 20 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.

## Speaker(s)



### SIUU Who? Best Practices and Limitations of the Scientific Information on Unapproved Uses Guidance

Olivia Estridge, PharmD

Director  
Jazz Pharmaceuticals, United States



### Speaker

Joshua Oyster, JD

Partner  
Ropes & Gray, United States

Josh Oyster is a partner in Ropes & Gray's Life Sciences Regulatory & Compliance practice. He steers clients through a wide range of FDA regulatory issues to help them bring innovative products to market while also ensuring regulatory compliance. Josh routinely helps companies navigate FDA inspections and other compliance and enforcement matters. He is frequently tapped to analyze clients' toughest questions related to complex or ambiguous regulatory requirements, drawing on his extensive experience with key policy and enforcement priorities, including medical product promotion, digital health, and data integrity. In addition, Josh assists clients in assessing regulatory risks associated with potential acquisitions and investments.

5:30 PM — 6:30 PM

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## Networking Reception

Day 2 Feb 24, 2026

7:30 AM — 3:25 PM

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## Meeting Registration

7:30 AM — 8:15 AM

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## Networking Breakfast

8:15 AM — 8:30 AM

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## Update from Ad Promo Working Group

Update from Ad Promo Working Group

### Session Chair(s)



#### Virginia Foley

Founder, CEO  
Compliance Forward, United States

Virginia Foley is the Founder and CEO of Compliance Forward, LLC, where she helps life-science companies navigate the intersection of compliance and innovation. A recognized thought leader and frequent speaker at industry forums, she brings over 20 years of Regulatory Advertising and Promotion experience from a variety of different pharma/biotech companies. She is a pioneer in the application of Large Language Models (LLMs) in Regulatory affairs. Besides being a Regulatory Ad Promo expert, her work style is grounded in creativity, strategic problem solving, and being natural leader and collaborator. Virginia lives in beautiful Northport, Michigan, where she enjoys being active outdoors year-round with her family and loyal Lab retriever.



#### Representative Invited

Merck, United States

Melanie Nasuti is a Senior Director, Advertising and Promotion Regulatory Affairs at Merck & Co., Inc. She leads a team of regulatory professionals who are responsible for the review and approval of promotional materials, and she is responsible for the U.S. promotional regulatory strategy for Merck's oncology collaborations and oncology pipeline products. Melanie has over 20 years of pharmaceutical industry experience including roles in regulatory affairs, global labeling, and medical affairs.

8:30 AM — 9:30 AM

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## Session 7: Mastering the Art of Promotional Review Committees: Strategies for Success

Unlock the secrets to navigating and excelling in the complex world of Promotional Review Committees (PRCs). This engaging session offers practical insights, proven strategies, and real-world best practices to help participants lead and contribute effectively to PRC discussions. Whether you're new to the process or looking to refine your approach, you'll gain the tools needed to ensure thorough, compliant, and impactful reviews that support strategic decision-making.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Identify the key components and roles within a Promotional Review Committee and understand their significance
- Apply effective strategies to prepare for and participate in PRC meetings, ensuring clear communication and compliance
- Develop best practices for evaluating promotional materials to achieve impactful review outcomes

## Session Chair(s)



### Anthony Genovese, PharmD

Group Leader, Regulatory Advertising and Promotion  
Johnson and Johnson, United States

Anthony Genovese is the Group Leader, Regulatory Advertising and Promotion at Johnson and Johnson. Prior to joining Johnson & Johnson, he held roles at Bayer Healthcare Pharmaceuticals, most recently serving as the Director of Regulatory Affairs – Advertising and Promotion and Head of Regulatory Advertising and Promotion Operations. Anthony has over 15 years of pharmaceutical industry experience including roles in medical affairs, external scientific affairs, and regulatory strategy.

## Speaker(s)



### The Art of Influencing Outcomes Without Formal Authority: Practical Strategies for Regulatory Affairs Leaders

#### Lynne Bolduc

Founder and Executive Coach  
Waverly, United States

Lynne is a Certified Professional Coach and the founder of Waverly, a bespoke executive coaching firm dedicated to the success and wellbeing of legal, regulatory and compliance leaders. She previously practiced law for 20+ years and spent over 15 years in the biotech/pharma industry, including as VP of Legal at Fortune 500 and mid-sized companies. With Waverly, her mission is to help legal, regulatory and compliance leaders transcend their expertise to unlock their leadership potential and impact. Lynne holds an LLB from Université de Montréal and a Graduate Certificate in Healthcare Compliance from George Washington University, and coaching certifications from the ICF, the NeuroLeadership Institute, iPEC and Hogan Assessments.



### Alana Goodman

Founder | Strategic Operations Consultant  
Phoenix BioPharma Groups, LLC, United States

## Refreshments, Exhibits, and Networking Break

### Session 8: Navigating Market Access and Payor Engagement Strategies: HCEI and PIE, Oh My!

As the healthcare landscape continues to evolve, timely and effective communication between life sciences companies and key stakeholders is critical to ensure patient access to innovative therapies. This panel will explore the regulatory frameworks and best practices surrounding the use of Real-World Evidence (RWE), Healthcare Economic Information (HCEI) and Preapproval Information Exchange (PIE) in support of market access strategies. Panelists will discuss how companies can responsibly share product value information with payers and healthcare decision-makers, while remaining compliant. The session will address challenges and opportunities for proactive, compliant engagement across the product lifecycle—from pipeline to post-approval.

Learning Objective :

- Understand the key types of data supporting payor communications, including RWE and HCEI
- Understand the current regulatory landscape governing communications with payors
- Guide compliant strategies for engaging payors in the pre-approval period
- Explore recent trends, guidance, and enforcement actions impacting market access communications

#### Session Chair(s)



#### Lynn Bowen, PhD

Vice President, Regulatory Affairs Advertising Promotion & Labeling  
Alkermes, Inc., United States

Lynn Bowen, PhD is currently the Vice President, Regulatory Advertising Promotion & Labeling at Alkermes. Prior to joining Alkermes, she was the Senior Director and US Head of Regulatory Advertising & Promotion at Vertex Pharmaceuticals. Lynn has over 15 years of pharmaceutical industry experience including prior roles in both regulatory and medical affairs. Lynn received her BS in Biotechnology from Rochester Institute of Technology and her PhD in Microbiology from Boston University School of Medicine.



#### Alyson Andrikanich, PharmD

Senior Director, Advertising and Promotion, Regulatory Affairs Americas  
Bayer Pharmaceuticals, United States

Alyson Andrikanich is a Senior Director in Regulatory Advertising and Promotion at Bayer Pharmaceuticals. She has over 15 years experience in the pharmaceutical industry, specializing in advertising and promotion in regulatory affairs. Alyson completed a post-doctoral industry fellowship program through Rutgers University and Bayer in Medical Communications/Medical Affairs.

## Speaker(s)



### Speaker

Alan G. Minsk, JD

Partner, Head of Food and Drug Team  
Arnall Golden Gregory LLP, United States

Alan Minsk is a partner and chair of the Food & Drug practice at Arnall Golden Gregory LLP. He advises pharmaceutical, biologic, medical device, cosmetic, food and dietary supplement companies on legal and regulatory matters relating to the U.S. Food and Drug Administration. He serves on the advisory board for the Food and Drug Law Institute's Food and Drug Law Journal (FDLI) and speaks frequently at conferences, conducts training webinars and in-house engagements. He advises life science companies and venture capital firms on regulatory matters involving acquisitions, divestitures, regulatory opinions, co-promotions and licensing agreements. Alan is recognized by Chambers & Partners "Who's Who Legal, and Best Lawyers."



### Speaker

Representative Invited

OneSource Regulatory, United States

11:30 AM — 12:30 PM

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## Luncheon, Exhibits, and Networking Break

12:30 PM — 1:45 PM

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## Session 9: Making an Impact, Compliantly, with Digital and Social Media Promotions

With the continuously evolving regulatory landscape, the future of digital and social media promotions is under greater scrutiny than for the last 20 years. We'll evaluate the impacts of enforcement actions on the digital and social media channel and platforms, how changes in DTC Advertisements affect short- and long-term video, and the trends and impacts of AI. Third-party content, organic vs. paid social media, and influencer engagement will also be evaluated as well as the changing nature of how HCPs and consumers are engaging with digital platforms and the impacts on promotional communications.

Learning Objective :

- Understand the unique environment of digital and social media for better compliance

- Make recommendations to their project owners about the opportunities and watchouts for promotion in digital and social media
- Predict the possible impacts of recent enforcement actions on digital and social media

## Session Chair(s)



### Zoe Dunn

President & CEO  
Hale Advisors, Inc., United States

Zoë Dunn has spent her career shaping how the life sciences industry looks at risk and marketing. She is the president and CEO of Hale Advisors, bringing to bear more than 20 years' experience in advertising and promotion governance strategy, as well as deep expertise in digital and creating readiness for omnichannel marketing, modular content, and GenAI content. Last year, Zoë penned the essential reference "Navigating the shift to omnichannel marketing" for Regulatory Focus, the peer-reviewed journal of RAPS, the Regulatory Affairs Professionals Society. MM+M acknowledged Zoë's industry contributions in 2024, naming her an MM+M Woman of Distinction. Zoë can be contacted at [zoe@haleadvisors.com](mailto:zoe@haleadvisors.com).



### Nicol George, PharmD, RPh

Executive Vice President, Promotional Review & Labeling Services  
ProPharma Group, United States

Nicol George, Pharm.D., R.Ph., is the Vice President, Promotional Review Services & Labeling at OneSource Regulatory (OSR) a ProPharma Group Company, where she manages the Regulatory & Medical Review staff, provides executive level consulting services including leadership mentoring, process improvements, electronic review system implementations & Advertising and Promotion Training. Before joining OSR, Nicol was at Baxter Healthcare where she held the position of Director, Global Regulatory Affairs Labeling, Advertising & Promotion & led an international team for 5 years (2012-2017). Nicol has been in the industry for over 20 years with pharma, biologic & device experience in Medical (Med Info & Medical Science Liaison) & Regulatory Affairs.

## Speaker(s)



### Speaker

### Melissa Sadowski

Director, US Advertising and Promotion  
EMD Serono, United States

Melissa Sadowski is a Director, US Advertising and Promotion in Global Regulatory Affairs at EMD Serono with more than 15 years of pharmaceutical industry experience. She has provided regulatory review and guidance for commercial and developmental products across therapeutic areas and led PRC operations teams.

1:55 PM — 3:10 PM

## Session 10: Telemedicine, Intended Use, and the Art of Staying Compliant

This interactive 75-minute session tackles the legal and compliance challenges that life sciences companies face when building pre-commercial strategies. We'll explore where disease awareness campaigns cross the line into promotion, how ad promo teams can shape development from TPP through Phase IV, and the evolving risks tied to telemedicine, Intended Use, and blurred roles between medical and commercial teams. Through real-world case studies, participants will learn to spot red flags and apply practical safeguards before a launch goes off track.

Learning Objective :

- Apply FDA, DOJ, SEC and OIG expectations to pre-commercial efforts, including Intended Use guidance and telemedicine marketing
- Evaluate how adpromo input from early development strengthens compliance and market readiness
- Recognize risk points when medical affairs and commercial teams overlap
- Practice compliance decision-making through interactive case scenarios adapted from real enforcement and legal actions

## Session Chair(s)



### Darshan Kulkarni, JD, PharmD, MS

Principal Attorney  
Kulkarni Law Firm, PC, United States

Dr. Kulkarni is Principal Attorney for the Kulkarni Law Firm which focuses on providing legal and regulatory solutions to pharmaceutical companies and their providers. He is a pharmacist & lawyer and advises clients on bringing their product to market, focusing on post IND thru commercialization and genericization.

3:10 PM — 3:25 PM

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## Closing Remarks

3:25 PM — 3:25 PM

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## Conference Adjourns