2ND ANNUAL

LIFE SCIENCE ADVERTISING & PROMOTION CONFERENCE

***VIRTUAL EVENT* | JANUARY 12-14, 2021**

MODULE 1

Tuesday, January 12, 2021 | 8:00AM - 12:00PM

***All times Central Standard**

8:00 ZOOM SIGN-ON & VIRTUAL COFFEE, FEATURING:
» Private & public text chat
» Interactive polling
» Tech check

8:25 Q1 PRODUCTIONS OPENING REMARKS & VIDEO PROGRAM WELCOME

GROUP DISCUSSION - CAMERAS ON!

8:30 OPENING GROUP DISCUSSION: SUCCESSFULLY RELOCATING PRC ACTIVITIES TO REMOTE WORK ENVIRONMENTS
Rapid and effective promotional review often includes in-person detailing and editing environments, but the rapid shift to remote work has forced the adoption of new collaborative work models. In order to preserve launch timelines without sacrificing accuracy and exhaustive review, ad promo teams must embrace digital solutions such as Marketing Content Management systems (MCMs), find ways to preserve open and candid dialogue through phone and video conferencing, and utilize tools for real-time change tracking, editing, and feedback.

9:15 KEEPING PACE WITH THE EVOLVING ROLE OF SOCIAL MEDIA IN ADVERTISING AND PROMOTION
- Managing uptick in social media chat traffic
- Entering new social media arenas (e.g. TikTok)
- Guidelines surrounding paid influencer partnerships
  - » Inclusion of all appropriate disclosures
  - » Ensuring influencer relevance to condition
  - » Influencer effect on widespread vaccine use
- Monitoring hashtags and controlling off-label messaging
- Ensuring patient privacy in targeted advertising

Erin Carducci, *Director, Regulatory Advertising & Promotion*
NOVARTIS

10:00 VIRTUAL NETWORKING & COFFEE BREAK

10:30 APPLYING INFORMATION GAINED FROM OPDP WARNING LETTERS FOR FUTURE AD PROMO EXCELLENCE
Warning letters from the Office of Prescription Drug Promotion (OPDP) can present opportunities far beyond remediation, including crucial material revaluation and improvement of wider product messaging. By contextualizing warning letters in the broader landscape of OPDP action, checking warning letter content against all extant promotional materials, and using the official OPDP lines of communication to build rapport with the office, life science companies can take full advantage of a necessary correction.

John Paul Marcus, *Director, Regulatory Affairs, Labeling, Advertising & Promotion*
HORIZON

11:15 MAINTAINING CONTINUITY OF AD PROMO ACTIVITIES DURING M&A AND STAFF REORGANIZATION
- Ensuring a stable core of PRC personnel throughout transitions
- Proactive alignment of PRC strategies between all merging parties
  - » Maintaining transparency re: timelines and goals with new members
  - » Synchronization of multiple eCTD management systems
- Preventing PRC expertise gaps with back-up member candidates

Jacob Nyman, *Director, Regulatory Affairs, Office of Promotion and Advertising Review*
MERCK

12:00 MODULE ONE CONCLUSION

A Special Thanks to our Sponsor:

framework solutions

FACILITATORS OF MODULE 1:

Erin Carducci
Director, Regulatory Advertising & Promotion
NOVARTIS

John Paul Marcus
Director, Regulatory Affairs, Labeling, Advertising & Promotion
HORIZON

Jacob Nyman
Director, Regulatory Affairs, Office of Promotion and Advertising Review
MERCK

Start a conversation

focused on learnings from the meeting's modules with fellow participants in our LinkedIn Group! Keep exchanging insights and best practices among peers, and take the opportunity to e-meet with delegates who focus on similar challenges to brainstorm together on topics that matter to YOU!

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MODULE 2

Wednesday, January 13, 2021 | 8:00AM - 12:00PM

***All times Central Standard**

8:00 ZOOM SIGN-ON & VIRTUAL COFFEE, FEATURING:
» Private & public text chat
» Interactive polling
» Tech check

8:25 Q1 PRODUCTIONS OPENING REMARKS & VIDEO PROGRAM WELCOME

8:30 FROM US AD PROMO TO INTERNATIONAL AD PROMO: KEY DIFFERENCES AND CHALLENGES
•Comparison and analysis of regulatory differences
  » FDA (US)
  » EFPIA (EU)
  » IFPMA (Global)
• Reviewing for global, regional and local country audiences
• Outline of requirements and best practices

Manfred Fleschar, *Group Lead, International Advertising & Promotion GI & Neuroscience, Global Regulatory Affairs* **TAKEDA**

9:15 FTC vs. FDA: NAVIGATING REGULATORY DISTINCTIONS AND OVERLAP IN COMMERCIAL AD PROMO ENFORCEMENT
• Clarifying lines of separate organizational jurisdiction
  » Over-the-counter vs. prescription medication
  » Oversight of print, digital, and television mediums
• Operating under the regulatory requirements of both agencies
• Distinctions between labeling and advertising regulations
• Identifying unique enforcement risks from each agency

Alan Minsk, *Partner & Leader, Food & Drug Practice Team* **ARNALL GOLDEN GREGORY**

10:00 VIRTUAL NETWORKING & COFFEE BREAK

10:30 CASE STUDY: OPTIMIZING THE HEALTH OF THE CONTENT MANAGEMENT PROCESS
Every organization should establish a program to perform ongoing monitoring of their content management processes (aka: PRC or MLR) to ensure that these critical business operations are performing at maximum capacity with high-quality outputs. Ideally, this monitoring program would include monthly activity data reports as well as an annual deep dive "Health Check" to benchmark the people, process, and technology associated with its execution. Attendees will review a case study that details the required planning and implementation of a monitoring program to optimize the efficiency, quality, and compliance of the content management process.
• Evaluating the health of the content management process
  » Benchmarking data
  » Summary of internal activity data
  » Industry Trend analysis
  » Technology reviews
• Required updates to process documentation
• Established education and training curriculum for all stakeholders
• Application of lessons learned

Rebecca Burnett, *Executive Director, Strategic Services* **FRAMEWORK SOLUTIONS INC.**

11:15 REGULATORY AND COMPLIANCE CONSIDERATIONS FOR ADVERTISING AND PROMOTION IN EHRs
Manufacturers are increasingly looking to electronic health records (EHRs) for ways to reach prescribers, through unbranded, branded, and patient access-related messaging and advertising. Each type of messaging contains unique risks based on the platform, including proper targeting of messages and fair balance. In addition, pharmaceutical manufacturer arrangements with EHR vendors, including clinical decision support (CDS) tools that may be embedded in EHRs and/or e-prescribing platforms, have come under scrutiny in light of recent enforcement. This panel will discuss regulatory and compliance considerations for:
• Concept discussions re: potential advertising & promotion in EHRs
• Contracting considerations for EHR-related messaging
• Regulatory basis for unbranded, branded, and patient access messages in EHRs;
• Overview of CDS and differences between EHR advertising and CDS
• Compliance considerations for field personnel and execution

Abe Gitterman, *Life Sciences/Healthcare Regulatory Associate,* **ARNOLD & PORTER**
Edgar Donohoe, *North America Compliance Lead,* **PFIZER**
Scot Kaselak, *Director of EHR Integration,* **BARDY DIAGNOSTICS**

12:00 MODULE TWO CONCLUSION

FACILITATORS OF MODULE 2:

Manfred Fleschar
Group Lead, International Advertising & Promotion GI & Neuroscience, Global Regulatory Affairs
TAKEDA

Alan Minsk
Partner & Leader, Food & Drug Practice Team
ARNALL GOLDEN GREGORY

Rebecca Burnett
Executive Director, Strategic Services
FRAMEWORK SOLUTIONS INC.

Abe Gitterman
Life Sciences/Healthcare Regulatory Associate
ARNOLD & PORTER

Edgar Donohoe
North America Compliance Lead
PFIZER

Scot Kaselak
Director of EHR Integration
BARDY DIAGNOSTICS

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***VIRTUAL EVENT* | JANUARY 12-14, 2021**

MODULE 3

Thursday, January 14, 2021 | 8:00AM - 11:15AM

***All times Central Standard**

8:00 ZOOM SIGN-ON & VIRTUAL COFFEE, FEATURING:
» Private & public text chat
» Interactive polling
» Tech check

8:25 Q1 PRODUCTIONS OPENING REMARKS & VIDEO PROGRAM WELCOME

8:30 PANEL DISCUSSION: CROSS-FUNCTIONAL PERSPECTIVES ON PROPER CFL GUIDANCE APPLICATION
- Real-world examples of successful CFL messaging
- Providing appropriate evidentiary CFL support
- Clarification on non-CFL information thresholds
- Distinction between additional context and new information

PANELISTS:
Gary Wieczorek, *Director Regulatory Affairs*
ABBVIE
Mary Kuskin, *Director of Regulatory Affairs (former)*
SAGE THERAPEUTICS
John Paul Marcus, *Director, Regulatory Affairs, Labeling, Advertising & Promotion*
HORIZON

GROUP DISCUSSION - CAMERAS ON!

9:15 SMALL GROUP DISCUSSIONS: IN-DEPTH EXPLORATIONS INTO CONSISTENT WITH FDA LABELING (CFL) GUIDANCE
- Viewing CFL guidelines by type of application
  - » Protocols for payer conversations
  - » Parameters of scientific exchange
  - » Patient advocacy communications
- Commonly encountered gray and undefined CFL areas
- Working collaboratively through hypothetical examples

MODERATORS:
Gary Wieczorek, *Director Regulatory Affairs*
ABBVIE
Mary Kuskin, *Director of Regulatory Affairs (former)*
SAGE THERAPEUTICS
John Paul Marcus, *Director, Regulatory Affairs, Labeling, Advertising & Promotion*
HORIZON

10:00 VIRTUAL NETWORKING & COFFEE BREAK

10:30 ADAPTING REVIEW METHODS AND CRITERIA FOR THE ASSESSMENT OF VIRTUAL CONGRESS BOOTHS AND MATERIALS
As conferences and congresses continue to shift from in-person settings to virtual platforms, life science companies must follow suit with display materials adapted for a digital environment. While the divide between commercial and medical is clear at physical venues, the line blurs in the digital realm, requiring ad promo teams to creatively delineate between arms of the company without sacrificing content and clarity.
Gina Vestea, *Senior Director Regulatory Affairs, Advertising & Promotion*
SANOFI

11:15 CONFERENCE CONCLUSION

FAQ

Our dynamic virtual event platform provides access to program content live and on-demand and connects you with peers. See our frequently asked questions and a detailed guide of how to access the virtual event features.

FACILITATORS OF MODULE 3:

Gary Wieczorek
Director Regulatory Affairs
ABBVIE

Mary Kuskin
Director of Regulatory Affairs (former)
SAGE THERAPEUTICS

John Paul Marcus
Director, Regulatory Affairs, Labeling, Advertising & Promotion
HORIZON

Gina Vestea
Senior Director Regulatory Affairs, Advertising & Promotion
SANOFI

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