Agenda

Day 1 — Wednesday, Oct. 15

8:00 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 9:45 a.m. **Pre-approval Communications**

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. – 10:30 a.m. **Disease Awareness Communications**

- A review of FDA's Help-seeking guidance
- Keys for using disease awareness communications prior to approval Essential information for continuing efforts post-approval compliantly

10:30 a.m. – 10:45 a.m. **Break**

10:45 a.m. – 11:15 a.m. **From Day of Approval through Commercial Launch**

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. – 12:00 p.m. **Essential Advertising & Promotion Regulations**

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 1:45 p.m. **Format-Specific Promotional Requirements**

- DTC Television Promotion

- Brief Summary Requirements for Print Promotion

1:45 p.m. – 2:30 p.m. **Substantial Evidence & Other Standards**

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:00 p.m. **Off-Label Information**

- Avoiding Off-Label Promotion
- Scientific Exchange Exemption
- Responding to Unsolicited Requests
- Distributing Off-label Reprints

4:00 p.m. – 4:30 p.m. **The Promotional Review Process**

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m. **Session Wrap-up, End of Day One**

<u>Day 2 — Thursday, Oct. 16</u>

8:30 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 9:45 a.m. **Integrating Digital Promotion**

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. – 10:15 a.m. **Social Media Part 1**

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 12:30 p.m. **Social Media Guidances**

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited

Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 3:15 p.m. **Promotional Review Board Practicum**

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. – 3:30 p.m. **Break**

3:30 p.m. – 4:15 p.m. **Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News**

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent venues for keeping up with these developments.

4:15 p.m. – 4:30 p.m. **Wrap-up and Adjourn Workshop**