ATTENDEE BENEFITS

- Better understand the FDA landscape and revised guidelines
- Discuss and examine case studies to identify how industry leaders develop compliant promotional practices
- Discuss ways to sync the availability of scientific and real-world data with the speed of regulatory action
- Analyze limitations and risks of off-label promotion
- Discuss challenges posed by the changing regulations of safety data and the implications of new guidelines
Dear Colleague,

A challenge faced by healthcare providers today is their ability to access relevant and truthful information about drugs and medical devices that they prescribe, as well as the extent to which they can provide adequate information that’s not available elsewhere. This has created a significant issue for public health, which has led to the demand for information outside of approved labeling. It has continued to rise, leading to the FDA’s current monitoring system, which prevents patients from receiving the information that they need to make well-informed decisions.

The 2018 Off-Label Regulatory Compliance Congress will continue the exploration of the amending regulatory landscape to gain a better understanding of how the industry can work with officials to expedite the transmission of relevant scientific information that advances public, including:

- Case studies identifying consequences and policy considerations associated with the revision of the definition of "intended use"
- Challenges posed by the changing regulations of safety data and the implications of new FDA guidelines
- Ways to sync the availability of scientific and real-world data with the speed of regulatory action
- The limitations and risks of off-label promotion
- Strategies to disseminate scientific findings to healthcare providers

And More!

Join industry leaders to further analyze today’s regulatory landscape in order to prepare solutions that will fast-track the progress and distributions of life saving treatments. This is truly a must-attend event for every pharmaceutical and medical device professional with responsibilities in regulatory affairs, compliance and/or promotion.

I look forward to welcoming you to Virginia this May!

Sincerely,

Bianca

Bianca Dux
Conference Production Director
ExL Events, a division of Questex, LLC
T: 917-242-3891 | bdux@exlevents.com

**WHO SHOULD ATTEND**

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- Regulatory Affairs
- Legal Affairs/Compliance
- Medical Affairs
- Marketing/Advertising and Promotion
- Sales
- Promotional Review
- Brand Management
- Medical Information
- Medical Education
- Medical Communication
- Product Training
- Commercial/Scientific Legal Affairs
- Quality Assurance

This event is also ideal for professionals from:

- Regulatory Affairs Service Providers/Consultants
- Compliance Service Providers
- Promotional Review Vendors
- Off-Label Service Providers
- Law Firms
- Marketing/Advertising Agencies

**SPONSORSHIP AND EXHIBITION OPPORTUNITIES**

Do you want to spread the word about your organization’s solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

To learn more about these opportunities, please contact Jon Mercado, Business Development Associate, at 917-932-0434 or jon.mercado@exlevents.com.

**Hilton Washington Dulles Airport**
13869 Park Center Road Herndon
Herndon, VA 20171

To make reservations, please call 703-478-2900 and request the negotiated rate for ExL’s May Meetings. You may also make reservations online at http://bit.ly/2BsFNeE. The group rate is available until April 20, 2018. Please book your room early, as rooms available at this rate are limited.

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To Register: Call 866-207-6528 or Visit www.exlevents.com/offlabel
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<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>8:00</td>
<td>Registration and Continental Breakfast</td>
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<tr>
<td>8:45</td>
<td>Chairperson’s Opening Remarks</td>
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<tr>
<td>9:00</td>
<td>Understand What the FDA Considers to Be Misleading vs. Truthful</td>
<td>Mary Ellen Dronitsky, Senior Director, Regulatory Affairs-Advertising and Promotion, AEGERION PHARMACEUTICALS</td>
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<tr>
<td>9:45</td>
<td>Considerations in the Promotion of Biologics in the Age of Biosimilars</td>
<td>Bruce A. Leicher, Senior Vice President and General Counsel, MOMENTA PHARMACEUTICALS, INC.</td>
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<tr>
<td>10:15</td>
<td>PANEL: Discuss the Implementation of Intended Use</td>
<td>Jennifer M. Williams PhD. JD. MBA. RN. MSM, Assistant Professor, UNIVERSITY OF SOUTHERN INDIANA</td>
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<tr>
<td>11:00</td>
<td>Networking Break</td>
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<tr>
<td>11:30</td>
<td>Developing Compliant Strategies in Disseminating Scientific Information to Health Care Providers: Addressing Risk in a CIA-Focused Environment</td>
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<td>12:30</td>
<td>LUNCHEON</td>
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<tr>
<td>1:30</td>
<td>Determine How to Reduce Risks Involved in Off-Label Promotion</td>
<td>Howard Dorfman, Distinguished Visiting Practitioner and Adjunct Professor, SETON HALL UNIVERSITY SCHOOL OF LAW</td>
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<tr>
<td>2:15</td>
<td>Supporting Product Claims Through Data Quality</td>
<td>Richard Liner, Senior Compliance Counsel, BAYER HEALTHCARE</td>
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<td>3:00</td>
<td>Networking Break</td>
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<td>3:30</td>
<td>The Current Position of Off-Label Use in the U.S.</td>
<td>Leslie Gladstone Restaino, General Counsel, VALIDUS PHARMACEUTICALS</td>
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<tr>
<td>4:15</td>
<td>Understand and Enhance Your Compliance Program With Off-Label Communication</td>
<td>Peter Lee, Vice President, Compliance, HERON THERAPEUTICS, INC.</td>
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<tr>
<td>5:00</td>
<td>Day One Concludes</td>
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</table>
8:30 Registration and Continental Breakfast

9:15 Chairperson’s Recap of Day One

9:30 PANEL: Discuss Non-Promotional Mechanisms for Disseminating Information and the Approval Needed

- Review best practices for navigating the tensions between FDA guidance’s and First Amendment rights
- Address the improvements needed to the communication channels between manufacturers and payers
- Discuss the need to communicate particular information to different categories of products, disease areas or patient populations

Jennifer M. Williams, Ph.D., JD, MBA, RN, MSM, Assistant Professor, UNIVERSITY OF SOUTHERN INDIANA
Howard Dorfman, Distinguished Visiting Practitioner and Adjunct Professor, SETON HALL UNIVERSITY SCHOOL OF LAW

10:30 Develop a Compliance Program that Includes Off-Label Communication

- Introduction to the guidelines and the roadmap for success
- Identify and Implement Measures that Reduce Risk
- Establish a framework of internal reporting and grow shareholder value

Jennifer M. Williams, Ph.D., JD, MBA, RN, MSM, Assistant Professor, UNIVERSITY OF SOUTHERN INDIANA

11:15 Networking Break

11:45 PANEL DISCUSSION: Explore the FDA Roll back on Off-Label Promotion

- Discuss the potential risk of liability for conduct that is lawful and beneficial to the public health
- Analyze what implications manufacturers could face to promote their products

If you are interested in joining this panel discussion please contact Bianca Dux directly, at bdux@exlevents.com.

12:45 LUNCHEON

1:45 A Year in Review – Looking Back on How the Regulatory Landscape Changed in the Past Year

- Reflect upon FDA’s evolving position on product communication between manufacturers and the public
- Review the draft guidances on manufacturer product communications
- Discuss FDA’s evolution on defining fair balance based on enforcement activity
- Explore strategies for the development of product communication that may be consistent with FDA-required labeling

Richard Lem, Assistant Director, Regulatory Affairs – Advertising and Promotion, BAYER HEALTHCARE

2:30 Determine How to Reduce Risks Involved in Off-Label Promotion

- Review best practices for navigating the tensions between FDA guidances and First Amendment rights
- Address the improvements needed to the communication channels between manufacturers and payers
- Discuss the need to communicate particular information to different categories of products, disease areas or patient populations

Sergio Alegre, Vice President, Global Compliance, OSMOTICA PHARMACEUTICALS

3:15 Recognize the Role of MSLs in Driving Physicians’ Off-Label Prescription Habits

- Discuss solutions to lack of safety information being shared
- Understand how misrepresentation actually harms patients
- Provide ethical tools and techniques to deliver patient-centric outcomes

Jacqueline Armani, Medical Science Liaison, Surgical, ALCON

4:00 Conference Concludes

“This conference, unlike so many others, was not just a lecture on low-level info (ex. guidance review). It provided real examples with open discussion.”
—Associate Director, Regulatory Affairs, TAIHO ONCOLOGY, INC.

“This event provided a helpful perspective from managed care pharmacy. Really appreciate the roster of speakers with different backgrounds and experience.”
—Corporate Counsel, PFIZER

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WAYS TO REGISTER

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Mail: ExL Events
494 8th Ave, Fourth Floor
New York, NY 10001
Fax: 888-221-6750

Registration Fees for Attending ExL's 2018 Off-Label Regulatory Compliance Congress:

EARLY BIRD PRICING Register by Friday, April 6, 2018

Conference $1,895

STANDARD PRICING Register After Friday, April 6, 2018

Conference $2,095

ONSITE PRICING

Conference $2,295

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Offers may not be combined. Early Bird rates do not apply. To find out more on how you can take advantage of these group discounts, please call 866-207-6528.

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SAVE 15%

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QUESTIONS? COMMENTS?

Do you have a question or comment that you would like addressed at this event? Would you like to get involved as a speaker or discussion leader? Please contact Conference Production Director Bianca Dux at bdux@exlevents.com.

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Analyze Today’s Landscape and Prepare Solutions That Fast-Track the Progress and Distribution of Life-Saving Treatments

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