5TH PROMOTIONAL REVIEW COMMITTEE COMPLIANCE & BEST PRACTICES

The leading event for uniting cross-team expertise, maximizing quality oversight during review and maintaining regulatory compliance in all multimedia promotional materials

ALL-NEW SPEAKING FACULTY AND SESSIONS REQUESTED BY YOU – OUR AUDIENCE!

- PRC Tactics for Biosimilars
- Urgent Response Tools for Label Changes
- Fine-Tune Compliance for Adaptive Websites
- Overhaul Training Standards for Your PRC
- Determine Proper Balance in Promotional Items for Managed Markets

PLUS!
UP-TO-DATE ANALYSIS OF YOUR SAFEST APPROACHES FOR COMPLIANT SCIENTIFIC EXCHANGE AND OFF-LABEL COMMUNICATION!

IN-DEPTH WORKSHOP
MAINTAIN PROMOTIONAL COMPLIANCE WITH FDAMA 114

"Innovative, educational, entertaining. The greatest benefit was hearing ideas and perspectives from other professionals and job functions in our industry."
—Senior Manager, Promotional Materials Compliance Management, SUNOVION

SPONSORS:

ELI LILLY Transitions Ad/Promo Submissions Through the eCTD Gateway
Josephine Secnik, Director, Ad/Promo Regulatory Affairs

LEO PHARMA Guides PRCs in Shaping Communication for Payers
Doreen Morgan, Vice President, U.S. Regulatory Affairs

SANOFI Ensures Compliant Materials for Use in Speaker Programs
Masha Chestukhin, Senior Manager, North America Compliance

DAIICHI SANKYO Increases Efficiency Through Early Concept Reviews
David Jacobs, Assistant General Counsel, Commercial Brands

PACIRA PHARMAceuticals Reviews Promotional Strategy After 1st Amendment Court Decisions
Anthony Molloy, Vice President, Legal & Compliance
DEAR COLLEAGUE,

Promotional review professionals have been challenged by many new regulatory developments in just the last 2-4 years, from the rapid growth of social media as a marketing platform, to the popularization of online regulatory submission, to the still-developing shockwaves released by 1st Amendment court decisions about off-label communication.

And while those new challenges have risen, PRCs have still had to face ever-present complexities of gathering and organizing input from multiple different areas of expertise, collecting the results, and making sure the review process advances smoothly and quickly.

ExL Events is proud to invite you to the 5th annual Promotional Review Committee Compliance & Best Practices conference – the only industry event devoted entirely to optimizing the roster, skill sets, teamwork, and speed of your PRCs. No other event goes into as much depth on these essential skills!

This year’s all-new agenda focuses on teaching you how to:

- Clarify the path for off-label messaging and scientific exchange after recent 1st Amendment court decisions
- Improve your promotional review approach to social networks and adaptive websites
- Ensure proper methods for regulatory submission through the E-2253 gateway
- Set best practice for the re-review and re-submission of content that had been approved in prior campaigns

Plus – an all-new, in-depth workshop devoted to maintaining promotional compliance under FDAMA 114!

I look forward to welcoming you to this unique learning and networking venue in October!

Sincerely,

Matt Greenbaum
Production Team Leader
ExL Events

VENUE

Wyndham Hamilton Park
175 Park Ave
Florham Park, NJ 07932

To make reservations, please call 973-301-9717 and request the negotiated rate for ExL’s 5th Promotional Review Committee Compliance & Best Practices or reference block code 10166880EL. You may also make reservations online at http://bit.ly/2rvDyoZ. The group rate is available until September 28, 2017. Please book your room early as rooms available at this rate are limited.

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WHO SHOULD ATTEND

This conference is tailored for professionals with the following titles and those with the following responsibilities:

- Promotion Review / Promotional Review / Promotion / Promo / PRC / MPRC / PMRC
- Material Review
- Regulatory Promotion & Advertising / PromoAd / AdProm / AdPromo
- Regulatory Affairs / Regulatory Process
- Compliance / Promotion Compliance / Promotional Compliance
- Labeling
- Medical Affairs / Medical Review
- Editor / Editorial Review / Copy Editing
- Medical Information
- Communications
- Medical Communications / Medical Information / Medical Science Liaison / MSL
- Medical Director
- Marketing / Marketing Operations / Marketing Communications / Marketing Services
- Commercial Operations
- Brand Manager / Product Manager / Brand Marketing
- Regulatory Affairs
- Legal Affairs / Counsel / Regulatory Counsel

This event is also of interest to:

- CRM / Data Management Software Suppliers
- MLR Process Vendors and Facilitators
- Advertising / Marketing Agencies
- Regulatory Consultants
- Medical Writing Firms
- Law Firms

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 us at 201 871 0474 or email register@pmaconference.com
WORKSHOP: FDAMA 114 – Promotional Review & Compliance Strategies
How straightforwardly can your teams communicate with payers or HCPs? Proper interpretation of FDAMA 114 has become a serious challenge for brand managers and Ad/Promo professionals. Typical promotional pieces are based on well-controlled clinical trials, but in the real world, such methodologies are not consistently applied.

- Clarify what submissions are in public domain when different companies have different approaches to real-world data
- Ask PRCs to interpret clinical trial results and apply fair balance to statements to HCPs
- Have PRCs clarify the intended audience for value messages
- Create new groups to specialize in health economics messages, so your sales team does not have these conversations
- Train reviewers on the methods used in real-world evidence for payers
- Bring in new levels of consistency for analysis
- Be aware of FDA enforcement of real-world evidence in conversations with payers
- Communicate data in a manner consistent with label, even if it isn’t included
- Work with outside counsel to go back through legislative history, even if it is poorly understood

Amy Van Sant, Director, Regulatory Advertising and Promotion, JANSSEN
* This workshop includes a 30-minute networking break

Transition Ad/Promo Submissions to the eCTD Gateway
There is much to be learned from case studies about the transition to eCTD submission for routine Form 2253 submissions, accelerated approval product pre-submissions, advisory comments, and other correspondence with OPDP.

- You need to maximize IT tool capabilities to allow for the creation of electronic promotional materials and overcome logistical hurdles for scheduling submissions with your publishing group.
- Review business process considerations, including organization change management, that ensure successful implementation of eCTD submissions
- Use “mock submissions” with OPDP’s eCTD submission group to ensure success in providing files
- Design a monitoring plan to track process performance and identify opportunities for improvement

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

Update Procedures After Changing Ownership of the PRC Process
If your company takes a new direction in managing the review process, with a new sub-team now responsible for driving it, then it is of the utmost importance that the person who catalyzes the review process takes responsibility for all quality issues.

- Not just for the final product but also for the need to only introduce materials that are at an acceptable level of effort and accuracy. The more the new process owners respect the order of item review, the faster things go.
- Empower reviewers to point out when re-submissions are necessary due to initial flawed approaches
- Hold people accountable for promo piece quality and process integrity
- Leave submission prioritization to the new process owners

Keri Shugrue, Senior Project Manager, Promotion Materials Compliance Management, SUNOVION

Chart a Path for Off-Label Communications in Light of Recent 1st Amendment Court Decisions
Even if you are right in the assumption that an off-label claim will turn out to be justified, an FDA pursuit can require a heavy expenditure of time and money to prove your case. As courts continue to make their rulings, how should you best proceed?

- File updated NDAs based on physician use of off-label indications
- DISCLAIM any off-label use in appropriate context
- Follow any new developments from FDA and market experts

Anthony Molloy, Vice President, Legal and Compliance, PACIRA PHARMACEUTICALS

Resolve the Future of Compliant Scientific Exchange
Although there have been a series of appellate court decisions addressing the limits of FDA control over communicating off-label scientific information, biopharma companies remain unsure of how to incorporate these decisions into a united policy. With significant risks facing companies whose policies and conduct may be seen as violating provisions of the FDA, the False Claims Act, and the anti-kickback statues, individual companies have been reluctant to press the issue aggressively.

- Use differences in patient populations and subpopulations studied in clinical trials to support appropriate dissemination of off-label scientific information
- Review emerging trends in speaker bureau training and presentations in light of continuing government oversight
- Interpret the various court decisions and subsequent FDA pronouncements and activities when developing a balanced approach to accurate and non-misleading scientific information

Howard Dorfman, Senior Corporate Counsel, EDGE THERAPEUTICS

Biosimilars Case Study: Alternate Engagement Models to Enhance Productivity of Internal Promotional Review Teams

Sameer Lal, Senior Vice President, INDEGENE

Prepare PRCs for Urgent Responses to Launches and Label Changes
Dealing with a new warning, contraindication or black box is totally different from a new indication or dosage change, in terms of urgency. The brand team will want to launch updated materials immediately, but there will be different, sometimes opposing internal pressures at work if new materials must be updated and printed to reflect new warnings.

- Reset what business partners want to accomplish in light of the need to react to label changes
- Prepare in advance for the worst-case scenario of responding to FDA warning letters
- Transfer the key lessons from new label creation when working with label updates

Jill Charbonneau, Director, Regulatory Affairs, AdProm, Product Launch & Labeling, MARATHON PHARMACEUTICALS

Leslie North, Vice President, Sales and Marketing, EAGLE PHARMACEUTICALS

Day One Concludes
FINE-TUNE YOUR SOCIAL MEDIA PROMOTIONAL STRATEGIES

9:00  Reorient Promotional Review Around the Assumptions of a New, Networked Generation
Having grown up with social media, Millennials can tell if something is organic or pre-planned, and most are not interested in interacting with pharma companies. Promotional campaigns based on lifestyle issues, such as contraception, can help in reaching the rising generation — but you must be able to speak their language without resorting to cliché and without forgetting compliance.
- Reshape messages into shorter running times
- Demonstrate when products like IUDs bring value, but without making a quality of life claim
- Reach out through nontraditional media, such as film festivals, to raise brand awareness and loyalty

Cynthia Akue, Promotional Planner, ALLERGAN

9:40  Fine-Tune Compliance for Multi-Version Websites
Guidelines for digital content can be both flexible and subjective, and this is especially the case for multi-version websites. All aspects of their appearance and interface on multiple devices can be questioned. What control procedures do you follow around this, and is the overall product patient-driven or professional?
- Resolve whether reader explorations of your website risks their being diverted to other ones
- Avoid mixing branded and unbranded information in the same digital atmosphere
- Plan for changes to website wording based on device type
Ana Rasack, Regulatory Affairs Associate, HELSINN THERAPEUTICS

10:20  Devise a Spectrum of Approaches for Social Media
Social media remains a huge moving target for promotional compliance. With so many moving parts and small nuances involved, it can be difficult to determine how much risk your organization is willing to take.
- Learn from prior successes and failures
- Clarify organizational risk tolerances
Sergio Alegre, Vice President, Global Compliance, VERTICAL PHARMACEUTICALS

11:00  Networking Break

SET A CULTURE OF EXCELLENCE IN PRC TRAINING

11:30  Presentation by VEEVA

12:10  Set Appropriate Frameworks for Communications and Conversations with Payers
With limited guidance on what reimbursement information you can provide, where should you draw the line? Determining what compliant communications with payers should look like is difficult, especially for new or first-in-class products.
- Conceive what your managed markets can talk about, and in what timeframes
- Use limited guidance to interpret the presentations and conversations that are appropriate
- Make meaningful progress in a landscape without high-profile successes to learn from
Doreen Morgan, Vice President, U.S. Regulatory Affairs, LEO PHARMA
**EARLY BIRD PRICING**

*Register Before Friday, September 1, 2017*

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**STANDARD PRICING**

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**ONSITE PRICING**

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**GROUP DISCOUNT PROGRAM**

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 201 871 0474.

**SAVE 25%**

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

**SAVE 15%**

Can only send three? You can still save 15% off of every registration.

**TERMS AND CONDITIONS:** By registering for an ExL Events (“ExL”) event, you agree to the following set of terms and conditions listed below:

**REGISTRATION FEE:** The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

**PAYMENT:** Make checks payable to ExL Events and write C897 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

**Please Note:** There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

**CANCELLATION AND REFUND POLICY:** If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee)

**CREDIT VOUCHERS:** Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees’ behalf, the credit voucher will no longer be valid.

ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

Substitution Charges: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants. ExL Events’ liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

*The opinions of ExL’s conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.*

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Yes! Register me for the conference.
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Please contact me:
□ I’m interested in marketing opportunities at this event.
□ I wish to receive email updates on ExL Events’ upcoming events.

Conference Code: C897

OCTOBER 16-17, 2017 // WYNDHAM HAMILTON PARK // FLORHAM PARK, NJ

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