TOP REASONS TO ATTEND:

- Comply with standardization and evaluation regulations
- Enhance REMS efficacy with a comprehensive understanding of stakeholder needs and an empathetic strategy
- Maximize the impact of communications with best practices from marketing
- Evaluate REMS efficacy with proven and progressive methods and tools
- Ensure safe medication use by vetting consumer and health technologies

FEATURED STAKEHOLDERS INCLUDE:

**PHARMA**

- M. Soledad Cepeda  
  **JANSSEN PHARMACEUTICALS**
- Emily Freeman  
  **ELI LILLY & COMPANY**
- Karen Smirnakis  
  **BIOGEN**
- Rachel Sobel  
  **PFIZER**
- Carmit Strauss  
  **AMGEN**

**PATIENT ADVOCATES**

- Leslie S. Ritter  
  **SOCIETY FOR WOMEN’S HEALTH RESEARCH (SWHR®)**

**HEALTHCARE PROVIDERS**

- Rebekah Hanson  
  **UNIVERSITY OF ILLINOIS HOSPITAL & HEALTH SCIENCES SYSTEM**

**PHARMACISTS**

- Gerald K. McEvoy  
  **AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS**

**ACADEMIANS**

- Ruth S. Day  
  **DUKE UNIVERSITY**
- Michael Wolf  
  **NORTHWESTERN UNIVERSITY**

**SPONSORS:**

- Campbell Alliance  
  **INVENTIV HEALTH CONSULTING**
- Mckesson Specialty Health
- Mapi

TO REGISTER: Call +1 866-207-6528 or Visit www.exlevents.com/REMS
Dear Colleague,

Recently the FDA released guidance for the industry on REMS revisions and modifications. They also added useful resources and unveiled a suite of new improvements to their REMS website to make it easier to navigate.

With the impending onset of rigorous evaluation standards, the stakes of the industry to consider, if not directly involve, multiple stakeholders in the development of REMS programs are at an all-time high. Companies put themselves at risk if they fail to act on the FDA’s shift in focus when designing their REMS.

The 8th REMS Summit, taking place January 21-22, 2016 in Arlington, VA, is the leading forum for discourse on how to better accommodate the needs of an array of REMS stakeholders through the design of systems, processes, methods and components necessary for the implementation, evaluation and standardization of REMS. This conference provides the most up-to-date information on new regulations and clarifies their implications to your work. The summit focuses on the FDA’s progress toward the standardization and evaluation of REMS programs. In addition to the insightful educational platform of the summit, participants will benefit from its networking opportunities, interactive workshops and panel discussions.

Conference attendees will synthesize the impact of REMS programs on stakeholders, FDA regulations and available resources (e.g., technology, personnel, allies, etc.) to institute conditions essential for safe drug use and REMS compliance. Participants will also learn key methods for implementing, executing, assessing and modifying REMS, including leveraging strategic partnerships, instituting adaptive internal structures and streamlining processes.

We look forward to welcoming you to Arlington in January!

Sincerely,

Brian L Anderson
Conference Production Director

Scott Grossman
Division Head, Conference Production

VENUE
Sheraton Pentagon City
900 S. Orme St.
Arlington, VA

Room Reservations: If you require overnight accommodations, please contact the hotel to book your room. ExL Events has reserved a block of rooms at a discounted rate for conference participants. We encourage conference participants to make reservations by January 6, 2016. To make reservations guests can call 1-800-325-3535 and request the negotiated rate for "ExL's January Meetings."

ExL Events, Inc. is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus, or travel and events companies. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL’s reserved guest room block using the details provided.

TO REGISTER: Call +1 866-207-6528 or Visit www.exlevents.com/REMS
RISK MINIMIZATION: THE BURDEN WHILE MAINTAINING DUE DILIGENCE TO REQUIREMENTS AND METHODS THAT ALLEVIATE

1:30 Refine REMS with training and certification requirements and methods that alleviate the burden while maintaining due diligence to risk minimization

- Summarize the progress of the FDA’s REMS Integration Initiative
- Rank factors critical to REMS integration into healthcare systems
- Discuss methods to reduce data duplication and discrepancies
- Consider the range of healthcare system contexts affected by REMS
- Institute structures and standards to ensure fidelity to REMS
- Review tools and methods to ease pharmacists’ obstacles for REMS compliance
- Refine REMS programs using training and certification methods to alleviate the burden without compromising safety

Molly Billstein Leber, Manager, Drug Use Policy and Formulary Management, Yale-New Haven Hospital

2:45 Panel: The impact of REMS on healthcare systems

- Reduce the burden on stakeholders by integrating risk management into healthcare systems
- Examine the utility of information technologies in communications and compliance
- Engage stakeholders in developing modes of communication and risk management tools
- Ensure that accountability for risk management becomes part of delivering high-quality healthcare

Moderator
Thomas Felix, R&D Policy Director, Global Regulatory Affairs and Safety, AMGEN

Panelists
Rebekah Hanson, Clinical Pharmacist and Assistant Professor of Pharmacy, University of Illinois Hospital & Health Sciences System
Scott Wirth, Clinical Pharmacist in Oncology and Clinical Assistant Professor, University of Illinois Hospital & Health Sciences System

3:45 Case study: Lessons learned from the ETASU REMS program and three waves of evaluation surveys

- Explore challenges and solutions related to program implementation and evaluation
- Analyze evaluation findings and discuss triggers for action
- Incorporate proven approaches to understanding stakeholders’ perspectives

Joanna (Asia) Lem, Senior Manager, Epidemiology, Pfizer
Rachel Sobel, Senior Director, Epidemiology Group Lead, Pfizer

4:30 Extrapolate key practices from social marketing to improve message impact

- Learn practical applications of audience segmentation to REMS
- Identify opportunities and avoid pitfalls in REMS communications
- Determine relevant indicators of change
- Critique communications for visual and verbal effect
- Delve into the psychological and social factors that influence message reception
- Develop an evaluation process to measure the impact of communications
- Compose and rate strategic communication plans and messages for effect

Carmit Strauss, Global Risk Management Scientist, AMGEN

5:15 Chairperson’s closing remarks

“Discussions were great. Information was helpful.”
—Director, Regulatory Affairs, Mallinckrodt

“It was a great event to learn what different practice settings were doing to comply with REMS. I had the opportunity to network with leaders from industry as well as clinical practice experts.”
—Clinical Pharmacy Coordinator, Yale-New Haven
DAY TWO — FRIDAY, JANUARY 22, 2016

8:00   Continental Breakfast

8:45   CHAIRPERSON’S RECAP OF DAY ONE

9:00   UTILIZE THE PATIENT PERSPECTIVE IN DEVELOPING AND STRENGTHENING RISK MITIGATION TOOLS AND SYSTEMS
   • Learn how REMS programs impact patients, caregivers and families
   • Capture and incorporate patient perspective and feedback in the design, implementation and evaluation of REMS programs
   • Develop communication strategies to effectively educate patients and other stakeholders about safety concerns, improve compliance, and evaluate risks and benefits
   Leslie S. Ritter, Vice President, Public Policy, SOCIETY FOR WOMEN’S HEALTH RESEARCH (SWHR®)

10:00  CASE STUDY: DESIGN A REMS THAT REFLECTS GLOBAL RISK MANAGEMENT WHILE UNDERSTANDING ITS IMPACT ON A CROSS-FUNCTIONAL TEAM AND THE ORGANIZATION
   • Understand the strategy and process for developing a REMS that incorporates global risk minimization principles
   • Design and lead product-specific goal-centered REMS suited to cross-functional team implementation
   • Leverage the influence of company culture and foster necessary cultural changes
   • Prepare relatable communications that convey key points to C-level executives and corporate decision-makers
   • Integrate REMS and RMP by leveraging common principles
   • Ensure REMS fidelity and efficacy by factoring in the capacities of internal departments and external vendors
   Karen Smirnakis, Senior Medical Director, Safety and Benefit Risk Management, BIOGEN

10:45  Networking Break

11:15  ASSESS PATIENT COMPREHENSION AND MEMORY WITH A STRATEGIC TOOL SET
   • Explore new strategies for assessing patient comprehension and memory
   • Compare advantages and limitations of alternative tools
   • Modernize REMS by adopting best practices in study design and execution
   • Evaluate REMS outcomes for both efficacy and validity
   • Analyze REMS program challenges to identify solutions
   Ruth S. Day, Director, Medical Cognition Lab, DUKE UNIVERSITY

12:00  Luncheon

1:00   CASE STUDY: THE MOBILE APP AS A VIABLE REMS CHANNEL FOR HCPs AND PATIENTS
   • Analyze the current REMS channel landscape
   • Discuss the developmental and submission phases of a novel REMS channel, the Mobile Application
   • Review implementation challenges and preliminary stakeholder uptake data
   May Chan-Liston, Director, REMS Strategy, CELGENE CORPORATION

1:45   PANEL: THE IMPACT OF REMS ON PHARMACIES
   • Learn methods and technologies that facilitate the incorporation of REMS programs in pharmacies
   • Streamline audits through clear and timely communications to pharmacies
   • Overcome counterproductive ETASU and refine practices to optimize patient safety
   • Examine key points of standardization and Structured Product Labeling
   • Revamp training and certification while maintaining due diligence to risk minimization
   Moderator
   Kinnari Patel, Global Regulatory Lead, ASTRazeneca
   Panelists
   Mary Jo Carden, Vice President of Government and Pharmacy Affairs, ACADEMY OF MANAGED CARE PHARMACY
   Mandy C. Leonard, System Director, Drug Use Policy and Formulary Management, CLEVELAND CLINIC
   Gerald K. McEvoy, Assistant Vice President, AHFS Drug Information, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS
   Edward D. Millikan, Director, Product Development and Maintenance, eHealth Solutions; Clinical Informaticist, AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

2:45   CASE STUDY: AN EVALUATION OF ER/LA OPIOID REMS THROUGH A SUCCESSFUL INDUSTRY COLLABORATION
   • Discuss a concrete example of an evaluation design for an expansive REMS program
   • Assess the impact of a particular REMS on patient knowledge, prescriber knowledge, prescribing practices and health outcomes
   • Prepare for a single shared REMS program or a REMS program expansion by adapting key practices and tools
   M. Soledad Cepeda, Director, Epidemiology, JANSSEN PHARMACEUTICALS

3:30   CHAIRPERSON’S CLOSING REMARKS

3:45   Conference Concludes

“Very engaging speakers with the depth and breadth of knowledge and experience required to comment well on FDA’s standardization report.”
—US Regulatory Lead, AMGEN

“Being new to REMS, this conference provided tremendous knowledge and networking opportunity.”
—Client Services Manager, UBC

“Excellent, very thought-provoking, eye-opening and informative.”
—Senior Medical Director, BIOGEN

TO REGISTER: Call +1 866-207-6528 or Visit www.exlevents.com/REMS
### 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 $295 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

### 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.

### MEDIUM PARTNER

- PharmaVoice
- PharmaPhorum
- PM360
- Technology Networks
- Global Risk Community

### GROUP DISCOUNT PROGRAMS

- **SAVE 25%** For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four). 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, Inc. (“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, Inc. and write C635 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 attendee 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) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

**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, Inc. 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, Inc.

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL’s designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL’s designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. ExL EVENTS, INC. EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.
**RISK EVALUATION AND MITIGATION STRATEGY SUMMIT**

*Improve REMS Efficacy Through Strategic Design, Assessment and Communication to Optimize Drug Safety, Compliance and Patient Outcomes*

January 21-22, 2016 // Sheraton Pentagon City // Arlington, VA

---

**TO REGISTER:** Call +1 866-207-6528 or Visit www.exlevents.com/REMS