TOP REASONS TO ATTEND:

- Comply with standardization and evaluation regulations
- Enhance REMS efficacy with a comprehensive understanding of stakeholder needs
- Develop metrics to maximize the impact of communications
- 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
ASTRAZENECA

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
NORTHEASTERN UNIVERSITY
8th Risk Evaluation and Mitigation Strategy Summit

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!

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.

Who Should Attend?
This conference is designed for representatives from branded and generic pharmaceutical companies with responsibilities in the following areas:

- REMS
- Benefit/Risk Management
- Pharmacovigilance/Surveillance
- Medical Direction
- Quality Assurance
- Drug/Product Safety
- Clinical Risk Management
- Life Cycle Management
- Regulatory Affairs/Legal/Compliance
- Clinical Affairs
- Clinical Data Management
- Clinical Operations
- Clinical Risk Management Compliance
- Epidemiology/Pharmacoepidemiology
- Marketing

This summit is also of interest to:

- Risk Safety and REMS Service Providers
- Data Management Service Providers
- Dashboard and Metrics Service Providers
- Healthcare Information Marketing and Technology Providers
- Consultants
- Law Firms
### Day One — Thursday, January 21, 2016

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<tr>
<th>Time</th>
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<tr>
<td>8:00</td>
<td>Registration and Continental Breakfast</td>
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<tr>
<td>9:00</td>
<td>CHAIRPERSON’S OPENING REMARKS</td>
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| 9:15 | EVALUATE REMS EFFICACY USING PROVEN AND PROGRESSIVE METHODS | - Learn best practices in survey design and implementation  
- Highlight changes in regulatory expectations regarding modes of evaluation  
- Analyze the EMA’s RMM patient outcome indicators for relevance to REMS  
- Study methods social scientists use to document changes in human behavior  
- Incorporate principles of user-centered system design thinking  
- Develop or adapt metrics to evaluate risk minimization management tools
Emily Freeman, Risk Management/Global Patient Safety Scientist, ASTRAZENECA

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| 10:00 | CASE STUDY: PRE-IMPLEMENTATION PLANNING FOR THE EVALUATION OF REMS | - Establish goals and process metrics for quality, quantity and fidelity  
- Determine what data is necessary and methods for collection analysis  
- Apply key practices from the field of implementation science  
- Assess the alignment of available resources with evaluation strategy requirements  
- Ensure support from internal allies and integrate external partners as stakeholders
Michael von Forstner, Head of Pharmacovigilance, ACINO PHARMA

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| 11:15 | CONSUMER AND HEALTH TECHNOLOGIES THAT PROMOTE SAFE AND APPROPRIATE MEDICATION USE | - Describe current health system failures that lead to less-informed patients and ultimately concerns about product safety  
- Identify different lower and higher technology tools that can be integrated into clinical workflows at the point of prescribing to support proper medication use  
- Review evidence-based strategies that can promote medication counseling, patient education and the monitoring of higher risk medications
Michael Wolf, Professor, Medicine and Learning Sciences Associate Division Chief – Research Division of General Internal Medicine, Feinberg School of Medicine, NORTHWESTERN UNIVERSITY

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| 1:00 | 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  
Paul Seligman, Executive Director, Global Regulatory Policy, 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

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| 2:45 | 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

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| 4:15 | EXTRAPOLATE KEY PRACTICES FROM ADVERTISING 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

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| 4:45 | PROGRAM AND THREE WAVES OF EVALUATION SURVEYS | - 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

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### Feedback Quotes

**“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
8:00 Continental Breakfast

9:00 CHAIRPERSON’S RECAP OF DAY ONE

9:15 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

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 of report.”
—US Regulatory Lead, AMGEN

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

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  - 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 contact our offices at (201) 871-0474.

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