**7th Risk Evaluation and Mitigation Strategies Summit**

January 22-23, 2015 | Key Bridge Marriott | Arlington, VA

**Our Distinguished Speaker Faculty Discusses**

**Best Practices for REMS**

**Design**

- Meredith Smith
  - Director, US Drug Safety Strategy and Science
  - EMD Serono

- David Chonzi
  - Safety Science Leader for Immuno-oncology
  - Genentech-Roche

**Implementation**

- Rachel Sobel
  - Senior Director, Epidemiology
  - Pfizer

- Milbhor D'Silva
  - VP, Product Safety & Pharmacovigilance
  - Astellas

**Evaluation**

**Modification**

**HOT TOPICS**

- Analyze the FDA’s Newly Released REMS Standardization Report
- Understand the European Guideline on Good Pharmacovigilance Practices (GVP) — Module XVI — Risk Minimization Measures
- Modify a REMS to Expand Patient Access
- Discuss Lessons Learned from Various REMS Programs
- Highlight Best Practices for FDA Negotiations
- Assess Evaluation Tools to Measure and Strategies to Improve REMS Effectiveness
- Advance the Field of Pharmaceutical Risk Minimization Through the Application of Implementation Science Best Practices
- Discuss Ways to Better Integrate Risk Management into Healthcare, Pharmacy Systems and Clinical Practice
- Highlight Key Considerations to Collaborate Successfully in a Single Shared REMS

**Enhance your skill set by registering for an all-access pass:**

**Workshop A: REMS from A to Z**

- Kinnari Patel, Director, US Risk Evaluation and Mitigation Strategy, Bristol-Myers Squibb

**Join Our Leading REMS Experts:**

- Michael Cheung, Project Manager in Medical Affairs/Risk Management, Vivus
- T Craig Cheetham, Research Scientist II, Kaiser Permanente Research
- Alicia Gilsenan, Senior Director Epidemiology, RTI Health Solutions
- Michael Wolf, Professor of Medicine and Learning Sciences, Associate Division Chief, Northwestern University, Feinberg School of Medicine
- Ruth S. Day, Director, Medical Cognition Lab, Duke University
- Cynthia Kear, Senior Vice President, CAFP/Project Lead, CO*RE (Collaboration for REMS Education)
- Molly Billstein Leber, Clinical Pharmacy Coordinator, Yale-New Haven Hospital
- Emily Freeman, Director Epidemiology - Health Behavior & Program Evaluation, Pfizer
- Paul Seligman, Executive Director Regulatory Affairs, Amgen
- Gary Appio, Head, US Safety Risk Management, Novartis
- Brian J. Malkin, Partner, McGuireWoods
Dear Colleague,

The 7th Risk Evaluation and Mitigation Strategies Summit once again brings an impressive lineup of REMS experts together to discuss best practices for REMS design, implementation, modification and evaluation.

The most experienced professionals from a cross section of small to large companies, pharmacy organizations, academia, hospitals and government agencies share their perspectives and experiences on how to improve REMS effectiveness. In an interactive workshop, newbies can get up to speed and learn all there is to know about REMS. The main summit features high-level panel discussions, case studies and presentations, which address the major challenges of working in a single shared REMS, negotiating with the FDA and managing the burden in pharmacy practice.

Hear from companies such as Pfizer, Vivus, BMS, EMD Serono, Genentech-Roche, Astellas and Novartis and many more about their processes and lessons learned from various REMS programs. Additionally, find out about cutting-edge research from leading scientists from Kaiser Permanente, Northwestern University, Feinberg School of Medicine and Duke University and learn how to overcome challenges in pharmacy practice from CO*RE (Collaboration for REMS Education) and Yale-New Haven Hospital representatives.

The conference has the most thorough updates on the FDA’s findings and global regulatory developments, and their impact on the industry. No matter if you are a REMS veteran or an absolute novice, this conference offers valuable insights on recent developments, paired with the opportunity to network and share with peers what has worked and what has not.

We look forward to meeting you in January!

Kai Hahn
Senior Conference Director
EXL Pharma

Who Should Attend
This conference is designed for VPs, Dept Heads, Directors and Managers of Medical Device, Pharma and Biotech companies whose responsibilities include:

- REMS
- Risk Management
- Pharmacovigilance/Surveillance
- Epidemiology/Pharmacoepidemiology
- Pharmacoeconomics
- Quality Assurance
- Drug/Product Safety
- Clinical Risk Management
- Lifecycle Management
- Regulatory Affairs
- Clinical Affairs
- Clinical Data Management
- Clinical Operations
- Clinical Risk Management Compliance
- Medical Writers/Communications
- Marketing
- Branding

This event is also of interest to:

- REMS/Drug Safety Service Providers
- Contract Research Organizations
- Data Management Services
- Technology Vendors
- Pharmaceutical Consultants
- Drug Safety & Risk Management Services
- Health Care Regulators and Policy Makers
- Health Services Research and Academics
- Lifecycle Management Services
- Speaker Bureaus

Sponsorship & Exhibiting 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 Pharma will work closely with you to customize a package that will suit all of your needs. To learn more about these opportunities, please contact:

REGISTER BY DECEMBER 5, 2014 and save with our early bird pricing as well as our great group discounts.

Media Partners

[Logos and links to various media partners]
DAY ONE PRE-CONFERENCE WORKSHOP / THURSDAY, JANUARY 22, 2015

9:00 REMS FROM A TO Z
This interactive workshop gives attendees a thorough overview of the different REMS components, as well as best practices for REMS design, implementation and evaluation. Walk away with effective strategies regarding how to tackle the numerous challenges of REMS programs.
» Outlining the different types of REMS from med guides only to more complex programs that include communication plans and EASU
» Assessing the different elements of a REMS program
» Using technology to leverage your REMS
» Learning best practices for communicating with the FDA and modifying your program continuously
» Implementing processes and workflows in your company
» Evaluating if the REMS is meeting its goals
» Addressing challenges and effective methods to overcome them

Kinnari Patel, Director, US Risk Evaluation and Mitigation Strategy, BRISTOL-MYERS SQUIBB

12:00 Lunch for Workshop Attendees

DAY ONE MAIN SUMMIT / THURSDAY, JANUARY 22, 2015

12:00 Registration for Main Conference Participants

4:00 ASSESS THE EUROPEAN GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP) — MODULE XVI — RISK MINIMIZATION MEASURES
» Explore the selection of tools and effectiveness indicators
» Understand the EU regulatory network
» Highlight elements that can be leveraged for REMS

Alicia Gilsenan, Senior Director Epidemiology, RTI - HEALTH SOLUTIONS

Emily Freeman, Director Epidemiology - Health Behavior & Program Evaluation, PFIZER

4:45 CASE STUDY: PFIZER'S EXPERIENCE WITH ALIGNING REMS AND RMMS
» Compare FDA REMS and EMA RMP requirements for products recently approved by both regulatory authorities
» Outline Pfizer’s interpretation of the new Risk Minimization Measure (RMM) European guidance (Module 16) and updated US FDA REMS Guidance
» Describe effective processes for risk minimization evaluation using real-life examples

Rachel Sobel, Senior Director, Epidemiology, PFIZER

5:30 ROUNDTABLES
In this interactive session you will get a chance to discuss your REMS program with peers and exchange views, find out what did and didn’t work for others, and learn how they have tackled various challenges.
Discuss Ways to Better Integrate Risk Management into Healthcare and Pharmacy Systems and Clinical Practice
Led by: Gary Appio, Head, US Safety Risk Management, NOVARTIS
Lessons Learned from Various REMS Programs
Led by: Milbhor D’Silva, VP, Product Safety & Pharmacovigilance, ASTELLAS
Highlight Key Considerations to Collaborate Successfully in a Single Shared REMS
Led by: TBD

3:30 Afternoon Networking and Refreshment Break
8:00 Registration & Continental Breakfast

8:55 Recap of Day One

9:00 Case Study: Modify a REMS to Expand Patient Access — The Qsymia Case Study
» Strategies used to build the REMS modification proposal
» Strategies used to optimize the REMS modification proposal presentation to the FDA
» Best practices for meetings and negotiations with the FDA
» Implement the approved REMS modification

Michael Cheung, Project Manager in Medical Affairs/Risk Management, Vivus

9:45 Panel Discussion: Assess Evaluation Tools to Measure and Strategies to Improve REMS Effectiveness
» Innovative strategies to evaluate a REMS program
» Identify areas for improvement from tools to measurements
» Involve key stakeholders in the process
» Analyze various approaches on how to modernize your REMS

Moderated by: Gary Appio, Head, US Safety Risk Management, Novartis
Panelists: David Chonzi, Safety Science Leader for Immuno-oncology, Genentech - Roche
Ruth S. Day, Director, Medical Cognition Lab, Duke University
T Craig Cheetham, Research Scientist II, Kaiser Permanente Research

10:30 Morning Networking and Refreshment Break

11:00 Advancing the Field of Pharmaceutical Risk Minimization Through the Application of Implementation Science Best Practices
» Highlight commonly encountered challenges and gaps in the design, implementation and evaluation of pharmaceutical risk-minimization initiatives
» Outline key best practices from the field of implementation science that can be leveraged for REMS and EU Risk Minimization programs
» Assess current practice in the US and the EU through a gap analysis and present case examples of risk minimization programs that could have been improved with strategic planning approaches

Meredith Smith, Director, US Drug Safety Strategy and Science, EMD Serono

11:45 Leverage Consumer and Health Technologies to Promote Safe, Appropriate Medication Use
» Describe current health system failures that lead to less-informed patients and ultimately medication safety and adherence concerns
» 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 various evidence-based strategies that can promote medication counseling, patient education and 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

12:30 Networking Luncheon

1:30 The ER/LA Opioid REMS: Lessons From the Front Lines
» Why this REMS is landmark
» Who is CO*RE and what they are doing
» Lessons learned (challenges, solutions, best practices)

Cynthia Kear, Senior Vice President, CO*RE

2:15 Present a Unique Set of Tools to Assess Comprehension and Memory for REMS
» Highlight innovative strategies to evaluate a REMS program and its effectiveness
» Introduce a unique set of tools
» Identify areas for improvement
» Analyze various approaches on how to modernize your REMS

Ruth S. Day, Director, Medical Cognition Lab, Duke University

3:00 Afternoon Networking and Refreshment Break

3:30 Case Study: Outline the Findings of Kaiser Permanente’s Provider Reception Survey of REMS
» Outline how provider perceptions of REMS could have a major impact on their success
» Present results from a cross-sectional survey of providers about REMS
» Discuss findings and potential next steps

T Craig Cheetham, Research Scientist II, Kaiser Permanente Research

4:15 Overcome Challenges for REMS Implementation in Pharmacy Practice
» Measure the effectiveness of communication
» Balance the burden
» Address issues with data management
» Overcome challenges with REMS implementation

Molly Billstein Leber, Clinical Pharmacy Coordinator, Yale-New Haven Hospital

5:00 End of Summit and Closing Remarks

What Past Attendees Say

“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.”
— Molly Billstein Leber, Clinical Pharmacy Coordinator, Yale-New Haven Hospital

“Excellent, very thought-provoking, eye-opening and informative.”
— Karen Smirnakis, Senior Medical Director, Biogen Idec
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*Includes Sales Tax and Service Fees

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VENUE
Key Bridge Marriott
1401 Lee Highway
Arlington, VA 22209

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7TH RISK EVALUATION AND MITIGATION STRATEGIES SUMMIT

Assess Regulatory Developments, Cutting-Edge Research and Effective Risk Minimization Tools from Related Disciplines to Improve the Effectiveness of REMS

January 22-23, 2015 | Key Bridge Marriott | Arlington, VA

OUR DISTINGUISHED SPEAKER FACULTY DISCUSSES

BEST PRACTICES FOR REMS

DESIGN

IMPLEMENTATION

EVALUATION

MODIFICATION