

2nd



Risk Evaluation and Mitigation Strategy

Innovation Summit

August 2-3, 2022

Hilton Alexandria Old Town, Alexandria, VA

Forward Planning Analysis, Innovation, Patient Centricity and FDA Compliance as a Strategic Framework To Execute Successful REMS Programs

SPEAKERS:



Anupam Agarwal
Former Vice President,
Global Head of
Drug Safety and
Pharmacovigilance
ZOGENIX



Jaylaxmi Nalawade
Associate Director
Pharmacovigilance
and REMS
LUPIN PHARMACEUTICALS



Carmit Strauss
Executive Director, Head of
Risk Management
and Organ Toxicity
TAKEDA



Jamie Wilkins
Head- Risk Management
Center of Excellence
Worldwide Safety
PFIZER



Matt Page
Team Lead, Center for
Post Approval Safety Studies
TAKEDA



Catina O'Leary
President and CEO
**HEALTH LITERACY
MEDIA**



Sheline Way
Associate Director,
REMS Operations
**TEVA
PHARMACEUTICALS**



Amanda Bulkley
Director
Clinical Research
UBC



Suzanne Marinello
Risk Management Lead
**THE JANSSEN
PHARMACEUTICAL
COMPANIES OF
JOHNSON & JOHNSON**



Kishore Gopu
Senior Director,
REMS Operations
**TEVA
PHARMACEUTICALS**



Kal Elhoregy
Director, Risk Evaluation and
Mitigation Strategy (REMS)
Programs - Regulatory
Affairs Clinical
**AMNEAL
PHARMACEUTICALS**



Bill Trombetta
Professor of Healthcare
Strategy and Marketing
**SAINT JOSEPH'S
UNIVERSITY**



Michele Riggen
Associate Director,
KAB Programs
UBC



Natalie Eiland
REMS Manager,
Contractor



Jacqueline Gerena
Director Program
Management
(REMS Program)
AIMMUNE THERAPEUTICS

TOP REASONS TO ATTEND:

- Evaluate the use of AI in REMS for the greater good of every stakeholder, from patients to the FDA involvement
- Optimize patient education, wellness and health literacy, the key elements to great and successful REMS programs
- Develop best practices on how to efficiently document Safety and Adverse Events on REMS while remaining FDA compliant
- Understand the impact and growth from telemedicine and how to accommodate in the REMS space
- Analyze assessment metrics and determine the processes of approval for REMS programs
- Review the evolution of REMS, success, pitfalls, room for improvement and the continued growth of the programs

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Risk Evaluation and Mitigation Strategy

Innovation Summit

Day 1: August 2, 2022

Day 2: August 3, 2022

7:45 am EST - Registration and Networking Breakfast

8:45 am EST - Chairperson's Opening Remarks

9:00 am EST - Topic TBD



Jamie Wilkins
Head- Risk Management Center
of Excellence- Worldwide Safety
PFIZER

9:45 am EST - Shared System REMS and Sponsor Management



Sheline Way
Associate Director,
REMS Operations
TEVA PHARMACEUTICALS

10:30 am EST - REMS Industry Consortium Session: Origins and Necessity of Creating the RIC and their Objectives and Plans for the Future in the REMS Space



Kal Elhoregy
Director, Risk Evaluation and
Mitigation Strategy (REMS) Programs
AMNEAL PHARMACEUTICALS



Kishore Gopu
Senior Director,
REMS Operations
TEVA PHARMACEUTICALS

11:15 am EST - Networking Break

11:45 am EST - PANEL DISCUSSION: Perspective Panel - A Review from All Stakeholders: Learn from the Pharma Companies, Pharmacies, Prescribers, Solution Providers and Patients on How to Build Successful REMS Programs



Natalie Eiland
REMS Manager
CONTRACTOR



Kishore Gopu
Senior Director,
REMS Operations
TEVA PHARMACEUTICALS



Catina O'Leary
President and CEO
HEALTH LITERACY MEDIA



Amanda Bulkley
Director Clinical Research
UBC

12:30 pm EST - Lunch Break

1:30 pm EST - Knowledge, Attitudes, and Behavior (KAB) Surveys "Don't let the word 'SURVEY' Fool you!"



Michele Riggen
Associate Director, KAB Programs
UBC

2:15 pm EST - Pharma Perspective on REMS KAB Surveys Challenges and New Opportunities



Matt Page
Team Lead, Center for Post Approval Safety Studies
TAKEDA

3:00 pm EST - Comparing US REMS and EU RMPs - The "Global" Effect on How to Handle Risk Management



Kal Elhoregy
Director, Risk Evaluation and
Mitigation Strategy (REMS) Programs
AMNEAL PHARMACEUTICALS



Jaylaxmi Nalawade
Associate Director
Pharmacovigilance and REMS
LUPIN PHARMACEUTICALS

3:45 pm EST - Networking Break

4:15 pm EST - Health Literacy Concepts for REMS Patients - Educate Your Patients so They Can Truly and Fully Benefit from the Program While Getting the Right Feedback From Them



Catina O'Leary
President and CEO
HEALTH LITERACY MEDIA

5:00 pm EST - Day 1 concludes

7:45 am EST - Registration and Networking Breakfast

8:45 am EST - Chairperson's Opening Remarks

9:00 am EST - Open Session Participation: Audits and Inspection Readiness on REMS Programs



Kal Elhoregy
Director, Risk Evaluation and
Mitigation Strategy (REMS) Programs
AMNEAL PHARMACEUTICALS

9:45 am EST - Integrating Electronic Health Systems - Reduce Burdens on Every Stakeholder



Jacqueline Gerena
Director, Program Management
(REMS Program)
AIMMUNE THERAPEUTIC

10:20 am EST - REMS as a "Value Based Arrangement" as Healthcare Transitions From Volume Based Healthcare to Value Based Care"



Bill Trombetta
Professor of Healthcare
Strategy and Marketing
SAINT JOSEPH'S UNIVERSITY

10:50 am EST - Networking Break

11:20 am EST - Incorporating Patient Perspective During the Development of REMS Elements/Tools and Educational Materials



Carmit Strauss
Executive Director, Head of
Risk Management and Organ Toxicity
TAKEDA

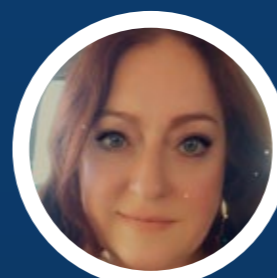
12:00 pm EST - Lunch Break

1:00 pm EST - REMS 15th Anniversary: Evolution, Innovation and Areas of Improvement



Anupam Agarwal
Vice President, Global Head of
Drug Safety and Pharmacovigilance
ZOGENIX

1:40 pm EST - Aspects to Consider When Developing a REMS Programs or Refining the REMS Processes



Suzanne Marinello
Risk Management Lead
Johnson & Johnson

2:15 pm EST - Modernizing REMS Programs, Exploring the Use of AI, Applications, Innovating to Better Serve the Patients and Everyone Involved

2:50 pm EST - NETWORKING BREAK

3:00 pm EST - Day 2 Concludes



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Hilton Alexandria Old Town, Alexandria, VA

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To take advantage of our discounted room rate [here](#) or call the venue 703 837 0440 and reference the event name.

The group rate is available until July 18, 2022.

Learn More



Groups discounts are available, if you wish to know more about them, please contact Frank Fernandez at frank@momentumevents.com

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