REMS Industry Consortium℠

*Innovating Patient Safety. Mitigating Risk.*

# All About the RIC

REMS Industry Consortium™
Innovating Patient Safety. Mitigating Risk.

# Who is RIC?

The REMS Industry Consortium is a nonprofit organization bringing together the perspectives of organizations that sell, or anticipate selling, prescription drugs or biologics subject to Risk Evaluation and Mitigation Strategies (REMS).

# Founding Companies

- Johnson & Johnson Innovation Medicine
- Jazz Pharmaceuticals
- Teva Pharmaceuticals
- Amneal Pharmaceuticals
- Bristol-Myers Squibb
- Viatris

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# Mission

The REMS Industry Consortium fosters collaboration and innovation to advance patient safety, appropriate access, and best practices in REMS-related drug and biologic risk management

# Vision

Improving patient safety and medication access through REMS innovation.

# Who is RIC for?

The REMS Industry Consortium (RIC) is for REMS Professionals who are seeking best practices and opportunities to advance patient safety, RIC provides an avenue for leaders to build intellectual capital, leadership, and strategic resources necessary for innovation.

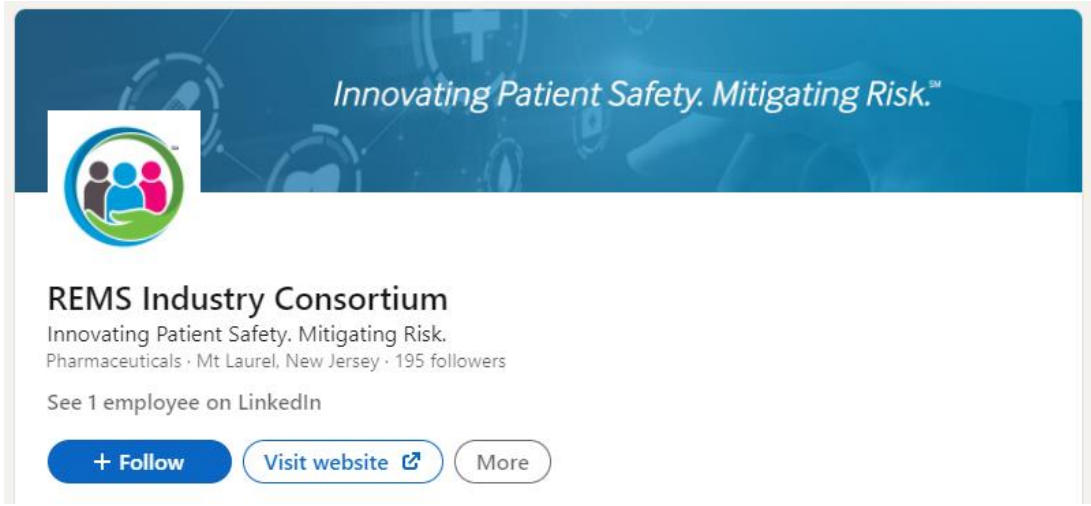
# RIC's Value Proposition (Company)

- Opportunity to help develop leading-edge REMS education to mitigate the challenges, costs and resources inherent in the REMS space (efficiencies in program set-up, design and maintenance)
- Join the collective voice of the industry in interactions with the FDA including feedback on draft guidances, and statutory issues specific to the REMS Industry
- Generate cost savings by reducing the time to market through shared best practices across organizations (including data compliance, reporting standards and innovation)
- Network with REMS industry professionals at programs (e.g. The RIC Annual Meeting and other exclusive knowledge sharing opportunities) providing access to human capital and training opportunities.
- Because REMS is a niche area, staying at the cutting edge of the field is critical. This unique consortium offers a specific focus on the specialty area.

# RIC's Value Proposition (Individual)

- Access to standards and best practices to guide REMS work
- Opportunity to network and build relationships with REMS industry professionals
- Opportunity to be a contributor in advancing the REMS industry

## RIC LinkedIn



# What we've done (to date)

- Created the Consortium with established bylaws, corporate governance and year over year increased membership (Started with 6 members in 2021, now RIC has 8 Board Members, 15 Manufacturing Members and 12 Industry Partners.)

# What we've done (to date)

- Established the RIC Annual Meeting as a forum for connecting the entire REMS Industry with input and participation from the FDA
  - 2023: 83 Attendees, including 5 from the FDA (Senior Regulatory Counsel, Office of Regulatory Policy; Director, Office of Medication Error Prevention and Risk Management; Senior Informatics Pharmacist, OSE/CDER/FDA; Director DRM | OSE, Associate Director)
  - 2024:  107 Attendees, including 8 from FDA (2 Division Directors; Deputy Director; Senior Clinical Informatics Pharmacist; Consumer Safety Officer; Regulatory Counsel; Associate Director for REMS Design and Evaluation; Team leader)

- Published a REMS 101 Course for those new to the industry. 100+ downloads YTD
  - https://remsconsortium.org/resources

# What we've done (to date)

- Developed the capacity necessary to gather feedback from stakeholder manufacturers, distill it, and submit it to the FDA
  - Submitted comments to guidance on *Changes to Third Party Vendors*;
  - Submitted comments to guidance on *FDA's Application of Statutory Factors in Determining When a REMS Is Necessary;*
  - Submitted comments to guidance on *Risk Evaluation and Mitigation Strategies: Modifications and Revisions and REMS Assessment;*
  - Submitted comments to guidance on *REMS Assessment: Planning and Reporting*
  - Submitted comments to guidance on *REMS Logic Model*

# What we've done (to date)

- **Established a trusting relationship with the FDA as the voice of the REMS Industry with the goal of helping to shape policy**
  - Bilateral Meeting February 24, 2023:  Claudia Manzo, Director, OMEPRM, OSE, CDER: Elaine Lippmann, Senior Regulatory Counsel, ORP, CDER: Michelle Eby, OSE, CDER: Laura Zande, Sevan Kolejan, Yasmeen Abou-Sayed, Jacqueline Sheppard, Paul Tran, Jo Wyeth, Naomi Boston, Carolyn Tieu, Shelly Harris, Zachary Oleszcuk, Barbara Bergquist, Christopher Nguyen
  - Bilateral Meeting September 26, 2024: Irene Chan, Elaine Lippmann, Michelle Eby, Cynthia LaCivita, Laura Zendel, Jacqueline Sheppard, Carolyn Tieu, Page Crew, Ed Millikan, Kim Lehrfeld, Madeleine Giaquinto, Joseph Paradis, Gita Toyserkani, Judine Berlus, Suzanne Robottom, Brian Gore, Tiffany Dominic
  - Next Bilateral meetings with the FDA are scheduled for March 18, 2025, and in September 2025

# Where are we going?

- Development of REMS Training Course with five distinct modules
  - REMS Design and Planning (Strategy) Launching 1Q 2025
  - Development (Pre-Launch) (2025)
  - General Operations (Launch/Maintenance) (2025)
  - Regulatory (FDA) Interactions (2025)
  - Shared REMS (2025)
- Will use the education modules above to develop an Education Program for REMS Professionals with a professional certification
- Online forum for members only to foster additional collaboration (Members only section of website)
- Implementation of an industry specific job posting forum to increase efficiency in filling open positions
- Access to industry-focused training and lobbying efforts through Buchanan, the Consortium's legal partner

# Working Groups

## Education/Certification Working Group

The Education/Certification Working Group is developing educational resources and RIC credentialing programs for various stakeholders, including the development of core curriculum and ancillary training modules. The Best Practices Working Group is a sub-group of this group and works to provide insight and guidance to the FDA Interaction Working Group as well.

## FDA Interactions Working Group

The FDA Interactions Working Group seeks to engage with the FDA by responding to FDA outreach on REMS-related initiative and preparing recommendations for the FDA on ideas generated by working groups and task forces.

## Communications and Marketing Working Group

The Communication and Marketing Working Group distributes RIC's thought leadership, promotes our work product and amplifies the RIC's voice in discussion of REMS industry priorities.

## Innovation & Technology Working Group

The Vendor, Innovation & Technology Working Group is exploring ways to increase vendor capabilities and identifying tactics to spur innovation and technology improvements.

# Education/Certification Working Group

The **Education & Certification Working Group** is developing a REMS Education program with five distinct modules. The first module should be launching in March 2025. Our ultimate goal is to create a REMS certification program for industry professionals. The five modules will include:

- REMS Design and Planning (Strategy)
- Development (Pre → Launch)
- General Operations (Launch → Maintenance)
- Regulatory (FDA) Interactions
- Shared REMS

The **Best Practices Working Group** is a subgroup of the Education & Certification Working Group that develops proposed standard timelines, definitions and submission content & consistent tactics for products with similar risk profiles.

# FDA Interactions Working Group

The **FDA Interactions Working Group** aims to provide a conduit between the REMS Industry and the FDA to allow for a more open and candid dialogue.  This is achieved through regular bilateral meetings, providing insight to the Best Practices Working Group on comments to guidances, and inviting FDA Participation and engagement at the RIC Annual Meeting. The next bilateral meeting with the FDA is being planned for March 18, 2025.

Influence the FDA and the future of REMS.  RIC members have the opportunity to engage directly with the FDA by responding to FDA outreach on REMS-related initiatives and preparing recommendations on ideas generated by working groups and task forces. Members can also interact with the FDA at the RIC Annual Meeting, held every year in Washington D.C., where FDA representatives gather in person to understand the needs of REMS professionals.

# Communications and Marketing Working Group

The **Communication and Marketing Working Group** distributes RIC's thought leadership, promotes our work product and amplifies the RIC's voice in discussion of REMS industry priorities.

The **Annual Conference Planning Task Force** is a subgroup of the Communication and Marketing Working Group that establishes, in alignment with the RIC Communications Plan, the vision, objectives and programming for the annual gathering of RIC members and industry stakeholders.

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# Innovation & Technology Working Group

The **Innovation & Technology Working Group** explores ways increase vendor capabilities and identifying tactics to spur innovation and technology improvements. This includes survey work among vendors and stakeholders, work towards data standardization, and gathering input from service providers and other non-manufacturing entities in the REMS space who have insight into best practices and issues facing the industry.

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# Membership Types

- Board and Founding Members
- Enterprise Members
- Group Members
- Industry Partners

# Board Members and Founding Members

- Participation in all Working Groups for unlimited number of members,
- Member discounts on Annual Conference Registration,
- Quarterly newsletter,
- Leadership positions available in Working Groups,
- The ability to set the strategic direction and specific objectives of the RIC's effort.
- Eligibility for election to Executive Committee positions within the RIC (Chair, Vice-Chair, Treasurer, Secretary)
- Board Dues: $50,000
- Founding Member Dues: $60,000
  - 23% reduction from 2023
  - $50,000 planned for 2027

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# Enterprise Members

- Participation in all Working Groups for unlimited number of members,
- Member discounts on Annual Conference Registration,
- Quarterly newsletter,
- Leadership positions available in Working Groups.
- Dues: $15,000

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# Group Members

- Participation in all Working Groups for up to 5 members,
- Member discounts on Annual Conference Registration,
- Quarterly newsletter,
- Leadership positions available in Working Groups.
- Dues: $5,000

# Industry Partners

- Sponsorship Benefits (Annual Meeting recognition and registration – dependent on level)
- Participation in the Innovation & Technology Working Group
- Invited participation in other working groups including the FDA Interactions Working Group.
- Dues dependent on Sponsor level:
  - Gold: $22,000
  - Silver: $11,000
  - Bronze: $8,250
  - Supporter: $3,850