

About the REMS Industry Consortium



Who is RIC?

The REMS Industry Consortium is a nonprofit organization bringing together the perspectives of organizations that commercializing (or are developing for commercialization), prescription drugs or biologics subject to Risk Evaluation and Mitigation Strategies (REMS).



Our Founding Companies

- Amneal Pharmaceuticals
- Bristol-Myers Squibb
- The Janssen Pharmaceutical Companies of Johnson & Johnson
- Jazz Pharmaceuticals
- Teva Pharmaceuticals
- Viatris



Our 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

Our Vision

Improving patient safety and medication access through REMS innovation.



Why Companies Need the RIC

- A trusted, reliable source of state-of-the art information on REMS issues
- Foster and encourage two-way communication between manufacturers/REMS sponsors and FDA
- Providing a collaborative, unified effort to assist in solving industry issues
- Members organizations have the opportunity to learn from peers in the development of their REMS programs



Why Individuals Need the RIC



Share best practices to guide REMS work

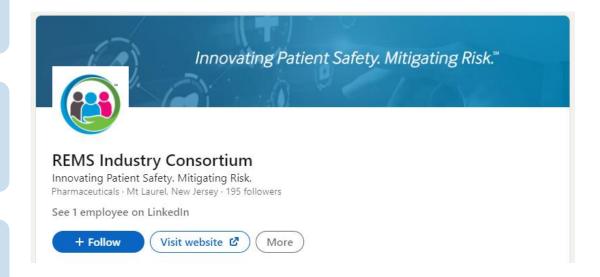


Opportunity to network and build relationships with REMS industry professionals



Opportunity to be a contributor in advancing the REMS industry

RIC LinkedIn





RIC Member Benefits

- Ability to contribute to REMS industry innovation and best practices through participation in Working Groups and Task Forces
- Contribution to the innovation and assist in mitigating the current and future challenges
- Exclusive knowledge-sharing opportunities through RIC-generated content
- Access to and opportunity to help develop leading-edge REMS education

As RIC grows, we will be adding industry-specific educational programs, training opportunities, networking cohorts and a regular stream of information to keep members up-to-date on regulatory and operational priorities.



Working Groups are at the Forefront of REMS Issues

Best Practices Working Group

Develop proposed standard timelines, definitions and submission content & consistent tactics for products with similar risk profiles etc.; leverage industry experience and identify tactics to streamline REMS program elements and enhance efficiencies for stakeholders (e.g. FDA, physicians, pharmacists, distributors, patients, caregivers, vendors). Create REMS best practices document package to include both FDA-focused (e.g. Shared System or Single Product REMS documents) and industry working group-focused materials (e.g. Confidentiality Agreement (CDA), REMS Participant Agreement (RPA)); coordinate with FDA Interactions & Standardization Working Groups as warranted.

Communications and Marketing Working Group

Conduct qualitative review and provide quality control and feedback for materials generated by task forces and working groups. Work with Marketing and Membership Task Force to develop a RIC communications plan. Publications = planning and strategy of scientific papers.

Collaborate with Buchanan/AH marketing staff by providing input on RIC branding and messaging. Develop profiles of members and potential members based on career stage, job title, function, etc. so that the membership offerings meet needs.



Working Groups are at the Forefront of REMS Issues

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.

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.

Vendor, 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.



Secure Your Membership Today!

Our initial membership offer is for <u>organizations that are commercializing</u> (or <u>are developing for commercialization</u>) FDA-approved pharmaceutical or biologic <u>products that are subject to REMS</u>. If that is not you, don't worry! We highly value our partners and will have expanded membership opportunities in the near future.

- How to become a member:
 - Apply via the Membership Application on RIC's website https://remsconsortium.org/membership-application