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).
- As a nonprofit, all records are public and the financials are audited by a third-party accounting firm annually.

Founding Companies

Johnson & Johnson Innovative 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.

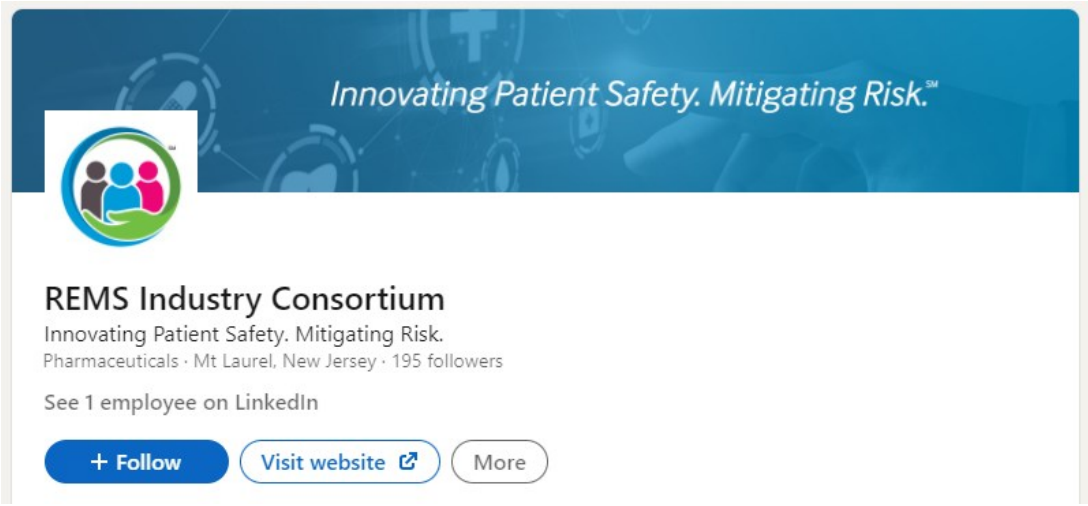
RIC's Value Proposition (Company)

- 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)

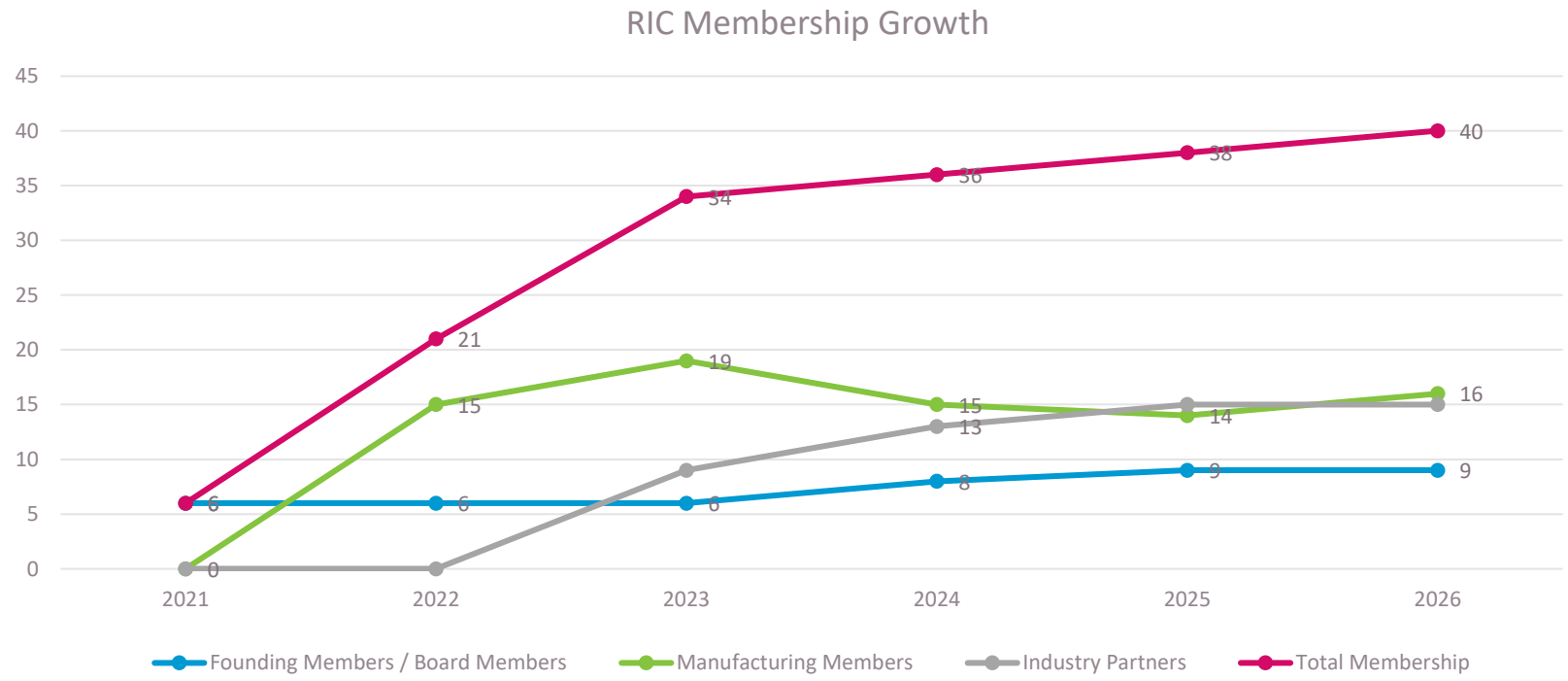
- Access to standards and best practices to guide REMS work
- Opportunity to network and build relationships with REMS industry professionals
- Opportunity to be a contributor in advancing the REMS industry

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 9 Board Members, 16 Manufacturing Members and 15 Industry Partners.)



What we've done (to date) - Education

- **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
  - **2024:** 107 Attendees, including 8 from FDA
  - **2025:** 117 Attendees, including 2 Transitioning FDA
  - **2026:** 113 Attendees, including 4 from FDA, 6 Transitioning FDA

- Published a REMS 101 Course for those new to the industry. 175+ downloads YTD
  - https://remsconsortium.org/resources

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What we've done (to date) – FDA interaction

- **Developed the capacity necessary to gather feedback from stakeholder manufacturers, distill it, and submit it to the FDA**
  - Submitted comments to the following FDA guidances:
    - Changes to Third Party Vendors
    - FDA's Application of Statutory Factors in Determining When a REMS Is Necessary
    - Risk Evaluation and Mitigation Strategies: Modifications and Revisions and REMS Assessment
    - REMS Assessment: Planning and Reporting
    - Reducing the REMS Assessment Burden
    - REMS Logic Model
    - Direct discussions on Application Orientation Meetings for REMS Programs.
    - Direct discussions on best practices development for sunsetting REMS Programs.
    - Direct discussions on modifications to the REMS Assessment reporting requirements

What we've done (to date) – FDA Interaction

- **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
  - Bilateral Meeting September 26, 2024
  - Bilateral Meeting March 18, 2025
  - Bilateral Meeting September 9, 2025
  - Bilateral Meeting March 10, 2026
  - *Next Bilateral meeting with the FDA scheduled for September 7/8, 2026*

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RAPS RECERTIFICATION APPROVED PROVIDER
Regulatory Affairs Certification (RAC)

What we've done (to date) – Accreditation +

- **Development of REMS Training Course with five distinct modules**
  - Module 1 - REMS Design and Planning (Strategy) Launched Q1 2025
  - ➔ Approved for **CEU** January 2026
  - https://remsconsortium.org/events-education/rems-training-courses-lms
- 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
- Industry-focused education & lobbying updates through Buchanan, the Consortium's legal partner
  - Session Q2 2025
  - Session Q1 2026

What we've done (to date) – Publications

- **Development of Whitepapers**
  - "REMS Inspection Readiness" – Q1 2026
  - "Strategy for Releasing a drug from a REMS Program" – Q2 2026
  - "Decommissioning a REMS" – Q4 2026

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Where are we going? – Accreditation +

- Development of REMS Training Course with five distinct modules
  - Module 2 - Development (Launch **w/CEU**) (Q2 2026)
  - Module 3 - General Operations (Launch **w/CEU** /Maintenance) (Q3 2026)
  - Module 4 - Regulatory (FDA) Interactions (Launch **w/CEU**) (Q4 2026)
  - Module 5 - Shared REMS (Launch **w/CEU**) (Q4 2026)
  - https://remsconsortium.org/events-education/rems-training-courses-lms
- Development of a **professional certification** from the REMS Training Course, the Education Program for REMS Professionals (started Q1 2026) (launch Q1 2027)
- Online forum for members only to foster additional collaboration *(Members only section of website)*

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 RIC events.
    - *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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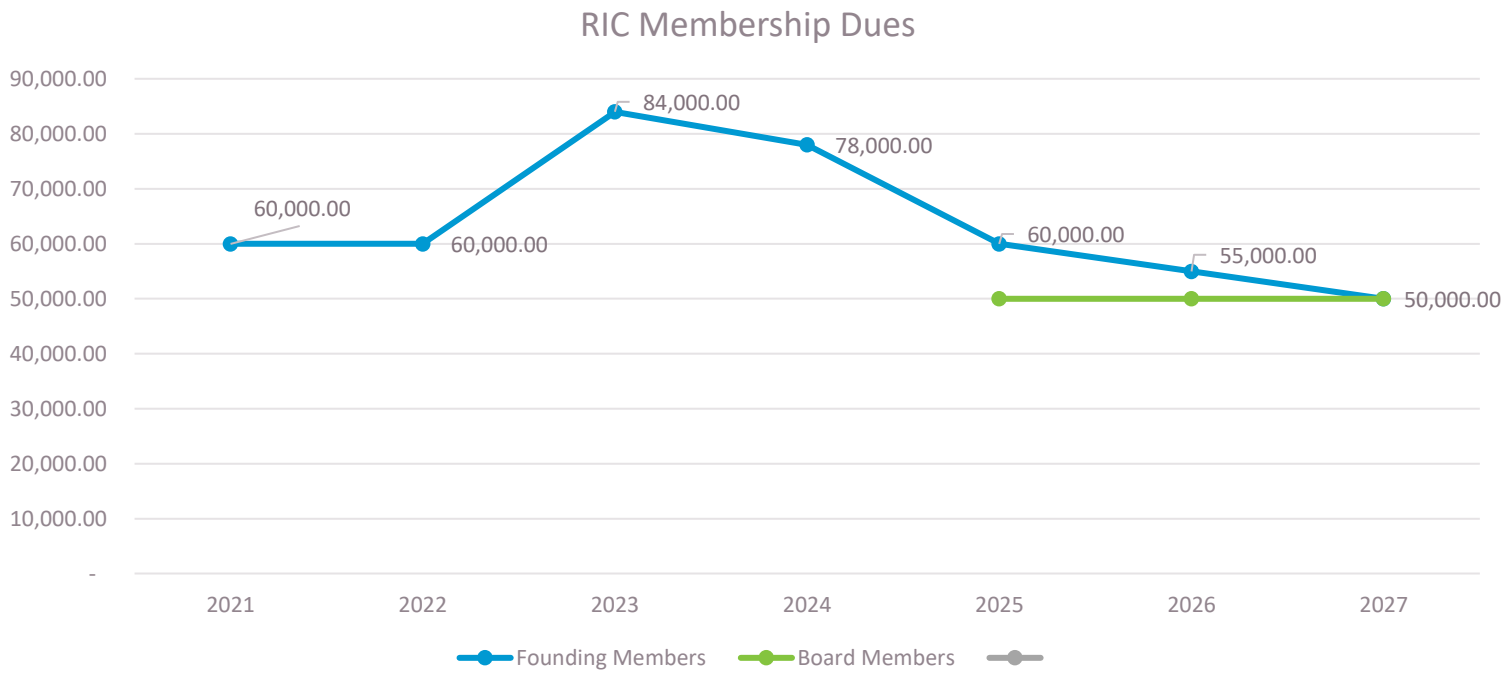
Membership Types

- Board and Founding Members
- Enterprise Members
- Group Members
- Pharmacy Partners
- Industry Partners
- Ex-FDA Individual Members

Membership Dues – Founding & Board Members



Dues for Founding and Board Members are projected to continue subsiding as the organization grows.

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Board Members and Founding Members

- Board Seat and 5 or more participants from organization
- 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)*
- 1 Board Member - Annual Meeting Registration
- Member Dues

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Enterprise Members

- 5 or more participants from organization
- Participation in all Working Groups for unlimited number of members
- Member discounts on Annual Conference Registration
- Quarterly newsletter
- Leadership positions available in Working Groups
- Member Dues

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Group Members

- 1-4 participants from organization
- Participation in all Working Groups for up to 4 members
- Member discounts on Annual Conference Registration
- Quarterly newsletter
- Leadership positions available in Working Groups
- Member Dues

Pharmacy Partners

Any Pharmacy organization engaged in a REMS Program, or considering engaging in a REMS program, which is aligned with RIC's mission and that the RIC Board of Directors approves for membership. Pharmacy Partners are ineligible to serve on the Board.

- Participation in the Innovation & Technology Working Group
- Invited participation in other working groups, including the FDA Interactions Working Group
- Non-Voting Member
- Member Dues

Industry Partners

Any organization (e.g. vendors or suppliers) that is aligned with RIC's mission, is eligible for Industry Partner membership upon approval of the Board of Directors.

- 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
- Non-Voting Member
- Industry Partners Sponsor levels:
  - Gold
  - Silver
  - Bronze
  - Supporter
- Dues (*Amount dependent on level)*

Ex-FDA Members

Any individual that has been previously employed by the U.S. Food & Drug Administration within the 12 months preceding the individual's initial membership date, and whose current employer is not the U.S. Food and Drug Administration nor a RIC Member.

- Participation in all Working Groups for up to 4 members
- Member discounts on Annual Conference Registration
- Quarterly newsletter
- Leadership positions available in Working Groups
- Non-Voting Member
- Excused from dues payment

What our Members and Partners Say

"The Board is willing to work with you, and we are working well together to standardize the process and try to simplify the REMS end-to-end, I truly appreciate and value being a RIC member " Keegan Chamberlain – Health Director, Regulatory Management – Cardinal Health

"Why be on the fence when you could be on the other side with us? Be part of that united collective that goes and partners with regulators and stakeholders to make REMS programs the least burdensome possible while maintaining patient safety as key, because patient safety and access is the reason why we do all of this" Jacqueline Gerena – J&J Director, Risk Management Strategy

"The best part of being a RIC member is the collaboration with other manufacturers, REMS administrators, FDA, wholesalers, distributors, and getting that insider knowledge, and hearing best practices and lessons learned that you can take back to your company" Jennifer Reinert – Pfizer Director, Risk Management Project Lead, Worldwide Safety & Regulatory

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1120 Route 73, Suite 200
Mount Laurel, NJ 08054

856.380.6894 | info@remsconsortium.org
remsconsortium.org