Take a deeper look with REMS 101

The REMS Industry Consortium is pleased to release a **FREE** resource for you to learn more about REMS and the REMS journey. Access this exclusive presentation at **remsconsortium.org**.

RIC: Innovating Patient Safety. Mitigating Risk.

Become a leader in REMS through the REMS Industry Consortium (RIC). RIC is a nonprofit organization bringing together the perspectives of organizations that are commercializing (or are developing for commercialization), prescription drugs or biologics subject to REMS. Learn more about **becoming a member** today!

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Phone: 856.380.6894 • Fax: 856.439.0525
Email: info@remsconsortium.org

TYPES OF REMS

SINGLE REMS:

- A program established and run by a single pharmaceutical manufacturer to manage the risks of a product, as part of a New Drug Application (NDA) or Biologics License Application (BLA).
- The REMS establishes the Goals of the program and what activities must be done by the manufacturer (i.e., education, monitoring, assessment, and other interventions) to mitigate a specific serious risk(s) listed in the labeling of the drug

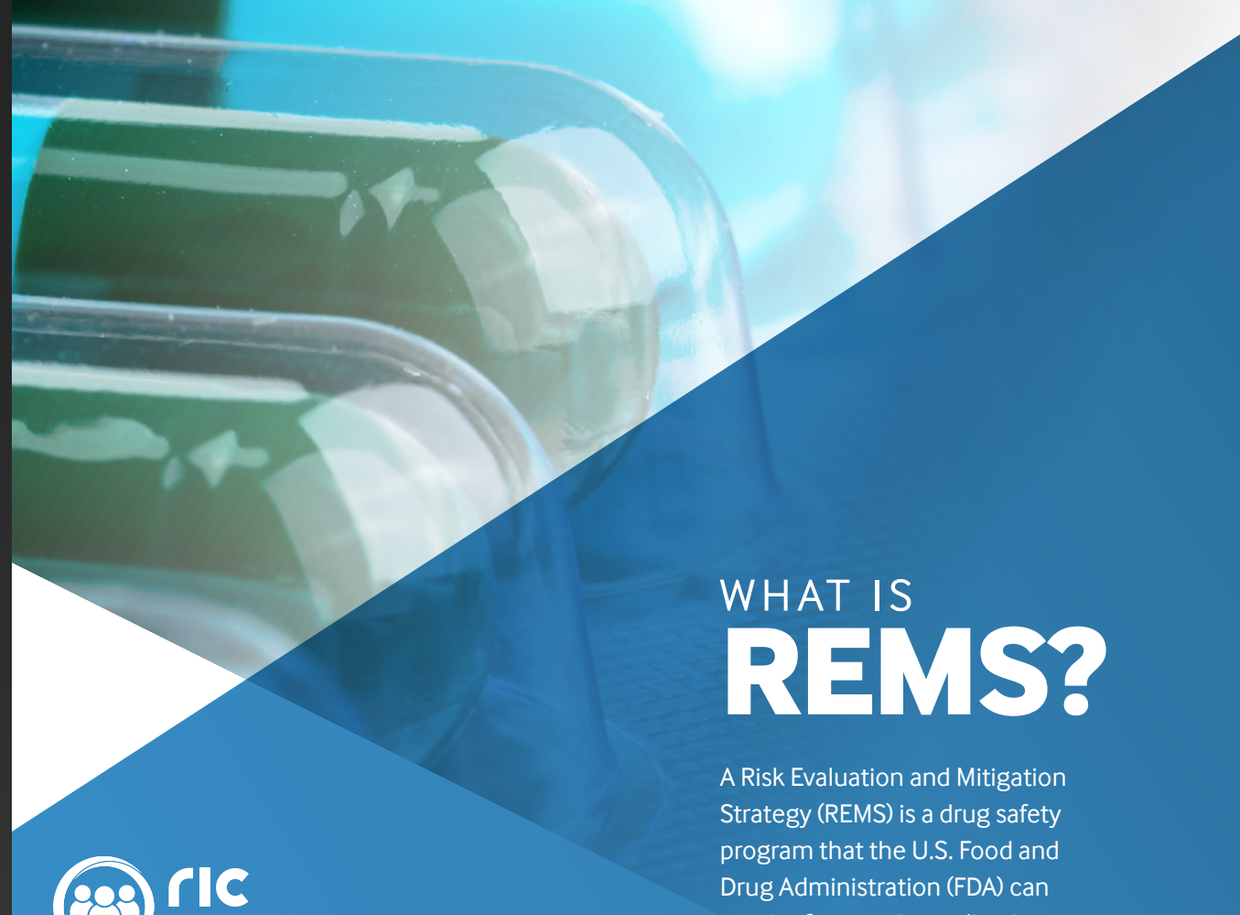
SHARED REMS: Encompasses multiple prescription drug products and is developed and implemented jointly by two or more applicants.

- Can involve multiple NDAs/BLAs or Abbreviated New Drug Applications (ANDAs)
- ANDA applicants may use a "single, shared system" REMS with the RLD or a "different, comparable aspect" of the ETASU (Parallel System [PS] REMS).

Components of REMS

ELEMENTS TO ASSURE SAFE USE: ETASU's are required medical interventions or other actions by healthcare professionals prior to prescribing or dispensing the drug. Some actions may also be required in order for the patient to continue on treatment.

OTHER COMPONENTS THAT MAY BE REQUIRED
Communication Plan, Implementation Plan, Assessments



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A GLANCE AT

Risk Evaluation and Mitigation Strategy (REMS)

WHAT IS REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

The FDA may require a REMS program before initial approval of a new drug application (NDA) - or after the drug has been approved should new safety information arise.

REMS JOURNEY

Expect to work with the following teams throughout the REMS development and operations process:
This may include your Regulatory, PV, Compliance, Legal, Finance, Commercial teams, REMS Administrator and other vendors, as required.

PRE-NDA/BLA/ETC. REMS REQUIRED

- FDA meeting
- Negotiations
- Identify REMS Core Team / REMS Resources

You should begin planning your REMS in the Pre-NDA/BLA application stage and/or early in the clinical research phase. Start having meetings with the FDA to discuss potential REMS requirements.

REMS DEVELOPMENT

- FDA communication
- REMS materials (Compliance Plan, Assessment Plan, etc.)
- REMS system (validation)
- HCP education

Once you receive your formal notification to have a REMS, here is where development of your REMS materials begins including the REMS Supporting Document, enrollment forms and educational materials, as applicable.

CHECKPOINT

DO YOU HAVE THESE ITEMS IDENTIFIED?*

- ❑ REMS Administrator and/or PMO
  - ❑ Technology/System
  - ❑ Call Center
  - ❑ Surveys
  - ❑ Audits
  - ❑ Patient Registry
- ❑ Design agency
- ❑ Distributors and Supply Chain
- ❑ Internal company partners

**As applicable depending on your REMS requirements, internal capabilities or vendors*

SPEED BUMP

REMS PREPARATION/ PLANNING

- Vendor contracts (MSAs, SOWs)
- Program Management

Assess your organization's resources and needs to determine what vendors you will need to contract with for REMS administration. A Program Management Office is a great way to help organize and manage your activities and vendors.

FDA REVIEW

- Back and forth revisions (materials, requirements)
- Negotiation

Throughout the REMS development process, expect to receive feedback and revisions from the FDA.

SPEED BUMP

CHECKPOINT

- ❑ Enrollment Form
- ❑ Medication Guide
- ❑ Website
- ❑ Training/Educational Materials
- ❑ Patient/HCP Guide

REMS IMPLEMENTATION

- REMS materials
- REMS system (data transfer/reporting)
- Additional support at launch / hypercare
- REMS training for your internal organization

Congratulations, your REMS is approved! Once your REMS is approved, it will need to be implemented. This includes launching your REMS system and sending out communications to educate and inform your stakeholders.

REMS MAINTENANCE

- REMS Assessment Report (Effectiveness Checks)
- Noncompliance monitoring
- Audits
- KAB surveys
- PSUR/PBRER
- Inspection Readiness
- REMS modifications/revisions

Here is where you'll complete your REMS Assessment Reports, be prepared for inspections, and submit any REMS Modifications or Revisions.

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Each phase could be in different order depending with each company.