



Coordinating Risk Evaluation and Mitigation Strategy (REMS) Activities

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Coordinating REMS activities between the various functional groups within a pharmaceutical company that are involved in, or are affected by REMS implementation planning can be a challenging task. How are the many activities going to be coordinated and managed when there are so many moving parts that need to be aligned prior to REMS submission to the FDA? Who should be responsible for managing all of these tasks? Since everyone already has their “normal day job” in preparing for a product launch, where do these additional activities fit in?

One specific task, REMS documentation, requires input and integration of clinical content, educational materials, and assessment protocols from different functional groups within a company. Since REMS is a relatively new FDA initiative, most companies do not have a single group charged with preparing the REMS document. Instead, a multifunctional team effort is needed involving multiple internal experts and effort that is above and beyond other daily activities of these contributors. The communications and collaboration between these functional experts may be the single most important element to assure the REMS document is ready for regulatory submission and ready to implement.

A second set of activities involves the coordination of REMS implementation with product launch preparations. Finding the proper balance that enables both standard drug launch activities and REMS activities to be carried out in a synchronized yet parallel fashion is an important aspect of REMS planning. Through balance, resourcing, thoughtful planning, and communications, the integration of REMS activities into the daily tasks of individuals can be less intimidating than it may first appear.

The frequency and forms of communications are an important variable to consider. Disrupting the normal workflow of activities of functional group contributors is a sure way to make any REMS documentation or implementation effort more complex and problematic. To avoid this, many factors need to be taken into consideration, such as:

- Which groups and delegates need to participate in which activities
- When they need to be involved
- The frequency of meetings
- Coordination across groups so interdependencies are addressed and a mutual understanding of the sensitivity and urgency of achieving milestones and deadlines is established

Consider this:

- Communications that are too frequent can become logistical hurdles due to scheduling conflicts of the necessary participants
- Insufficient communications increase the risk of losing harmonization (and cooperation) between groups.

Finding the proper balance that fits into the logistical and individual efforts of a REMS team is key to successful and timely REMS development and, ultimately, coordinated approval of products and the related REMS.

One approach to consider is establishing and operating a centralized “REMS Coordination Office”. Staffing of a REMS Coordination Office with internal staff, supplemented by experienced project managers and subject matter expertise, can help assure that all the activities critical for successful REMS submission and commercial launch take place.