



Ten Things to Consider When Developing a REMS

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1. **Patient Safety First.** There will be many competing priorities during the process of developing a REMS. The first priority must be patient safety.
2. **Create Options.** There is a temptation to evaluate the situation and define the “right” REMS design. In reality, there are many feasible options. The “right” option is the one that achieves your key objectives in a defensible, science-based way.
3. **Co-design with Stakeholders.** It is easier to develop your REMS program internally, but short-term expediency can lead to long-term problems. Instead, collaboratively design programs with stakeholders such as physicians and patients to assure the program elements are feasible, acceptable, and understandable.
4. **Use Science-Based Approaches.** There are many science-based methods that can support the development of a REMS. Failure Mode and Effects Analysis (FMEA), ethnography, and hazard assessments are all examples of effective techniques that help to define the critical points in the care process for intervention. These science-based methods create a more robust and defensible program.
5. **Consider Checks and Balances.** Do the people or consultants designing your REMS have a vested interest in the outcome of the design? You may want to consider an independent design firm and/or project management firm that can help to minimize design bias.
6. **Effective Education Techniques.** Adults learn most effectively from a blended approach to education. Consider using print, video, audio, and interactive methods to enhance the educational effectiveness.
7. **Enabling Tools.** The ultimate objective of a REMS is to guide behaviors of stakeholders in a way that minimizes risks. Describing the desired behaviors in an educational brochure is only a start. An enabling tool actually helps (or enables) the learner to apply the behavior in their everyday activities.
8. **Dedicated Project Management.** A REMS is often designed and implemented during the busiest time in the product lifecycle – at launch. Everyone already has a “day job” to commercialize the product; often the REMS program is resourced in the margins. It is essential to commit a dedicated resource to project manage the cross-disciplinary team of individuals who must develop and implement the REMS.
9. **Cross-Functional Sport.** Risk management is a cross-disciplinary activity that requires the insights and expertise of medical, marketing, regulatory, legal, safety, and many other perspectives. No other pharmaceutical endeavor requires this level of collaboration. Invest in managing and facilitating this cross-functional work.
10. **Contingency Planning.** Ultimately, the final decision about the acceptability of your REMS is in the hands of FDA, whose review and approval process for REMS is still evolving. Expect surprises. Prepare contingency plans to be able to rapidly respond to requests late in the review process. Mobilize a contingency team that is ready to customize and submit contingency modules that may be necessary to gain approval.