

Beckloff Associates

REMS Submissions and Management



REMS Submission and Management

. . . Satisfy FDA mandate for Risk Evaluation and Mitigation Strategy (REMS)

. . . Successfully manage REMS elements and timelines

What is a Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a recent and emerging regulatory requirement whereby the FDA expects pharmaceutical and biotech companies to monitor, submit plans, and proactively manage safety risks as part of NDA submission and life-cycle management. Common risk management issues have included drugs with abuse potential, risk of fetal abnormalities, risk of QTc prolongation, risk of hepatotoxicity, drug-drug interactions, and polymorphic metabolism. The REMS program may include elements to assure safe use, a communication plan, an implementation system, assessment tools, and a timetable for submission of assessments.

Who is it for?

Pharmaceutical and biotechnology companies who are required to submit and manage a REMS for their product per Federal Register notices, because of new FDA safety concerns, or who have been notified during the FDA review process that their products will require a REMS.

What is provided?

- Interpretation of FDA requests for REMS
- Preparation of REMS documents tailored to client drug products
- Preparation of tasks and timelines for successful implementation of REMS in partnership with client
- Pharmacovigilance oversight and postmarketing REMS element management
- Integration with reimbursement services

Contact Us:

To obtain more information, or to request a proposal for REMS Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web page at <http://www.cardinalhealth.com/beckloff>

Beckloff Associates

REMS Submissions and Management



REMS Solutions

- . . . Ensure timely FDA approval*
- . . . Reduce product launch delays*

Expertise:

- Clinical, Non-Clinical and Regulatory Affairs
- Significant label development experience
- REMS submission preparation
- REMS oversight and management
- Commercial launch readiness

Why Beckloff Associates?

- A track record of success spanning four decades
- Experience with all classes of pharmaceutical products
- A strategic global approach to regulatory planning and product development
- Successful relationships with regulatory agencies worldwide
- Continuity of service from the laboratory bench to the pharmacy shelf and beyond
- A commitment to quality, efficiency, and our clients' needs
- The leveraged resources of a Fortune 20 company

Contact Us:

To obtain more information, or to request a proposal for REMS Services, please contact Beckloff Associates at **913.451.3955**, or send an e-mail to **info@beckloff.com**, or visit our web page at <http://www.cardinalhealth.com/beckloff>