Metis Consulting Services: REMS offerings

WHO IS METIS?

Metis Consulting Services was founded to provide trusted advisory services to organizations within the Life Sciences Industry. Our experience spans from bench to post-approval services in the GXP space. We help clients leverage cross-functional expertise to efficiently develop their assets while anticipating and proactively addressing potential pain points along the way.

Mission:

Our mission is to ensure the planning and execution of quality, drug safety, pharmacovigilance, clinical, and data management have the tools to support innovation pathways, with a balance of humanity and lightheartedness along the way.

Risk Evaluation and Mitigation Strategy (REMS): REMS programs are designed to help ensure that the benefits of certain medications outweigh the risks. They can include a variety of requirements. The specific requirements of a REMS program will vary depending on the medication and the risks associated with it. We can assist with developing program specific workable solutions. Metis has partnered with RIC (REMS Industry Consortium), which includes the foremost experts in the field.

Risk Management Plans (RMPs):

Describes the risks associated with a medicinal product and the measures that will be taken to manage those risks. RMPs are required by regulatory authorities around the world for all new medicinal products, and they must be updated throughout the product's lifecycle as new information becomes available.

Pharmacovigilance risk management plans are living documents that should be updated regularly to reflect new information on the safety of the medicinal product. This information may come from clinical trials, post-marketing surveillance, or scientific literature.

SERVICES:

Metis offers the following services for Shared REMS programs: Trusted Advisory, PMO, audits, and education development.

For single REMS programs, Metis is a full service provider.

Metis offers end to end guidance and services for RMPs.

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