

METIS

Executive Summary

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 GXP space. We help clients leverage cross-functional expertise to efficiently develop their assets while anticipating and addressing potential pain points along the way.

SERVICES

Quality Assurance: We have a robust understanding of how the foundation and overarching responsibilities of Quality Assurance enable compliance with health authorities worldwide. Knowing where to go next in the process, and that all roles need a seat at the table is just the beginning.

Risk Management: Establishing a proactive approach rather than a reactive approach to product development includes risk management across the bench to bedside landscape. We combine our experience with guidance from Health Authorities and the goals of each client to enable efficient scalable processes.

Data Management: We have a dedicated data management team with the flexibility to support phase 1 to phase 4 trials. We provide side by side client support from establishment of the URL through validation, production, and data mining.

Pharmacovigilance: From first in humans through post-marketing, addressing pharmacovigilance is a critical piece of product development. Let us help you navigate the process.

REMS: How do Risk Evaluation and Mitigation Strategies (REMS) programs work? What are the implications? What responsibilities do organizations have when they have been assigned a REMS by the FDA? We can help. We work with RIC (REMS Industry Consortium), on cutting edge solutions.

Mergers and Acquisitions: After the ink is dry on the agreements, that is where we provide the plans for integration of data, departments, and personnel. Our expertise and due diligence ensures that any health authority or regulatory issues are addressed in a timely manner.

At METIS, our mission is to ensure 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.

 [MetisConsultingServices.com](https://www.MetisConsultingServices.com) | [linkedin.com/company/metis-consulting-services](https://www.linkedin.com/company/metis-consulting-services)

AUDITS | DATA MANAGEMENT | PHARMACOVIGILANCE | QUALITY MANAGEMENT | REMS