

METIS

Pharmacovigilance Services

Pharmacovigilance:

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The primary goal of pharmacovigilance is to enhance patient safety and ensure the benefits of medicinal products outweigh their risks. This field plays a crucial role in monitoring and improving the safety of pharmaceutical products throughout their life cycle, from development and clinical trials to post-marketing surveillance. It involves a multidisciplinary approach and requires ongoing collaboration between various stakeholders to maintain and improve public health.

Key activities in pharmacovigilance include adverse event reporting, signal detection, risk monitoring, audits, inspections, safety communications and training. Both biopharma companies and regulatory agencies conduct pharmacovigilance to protect patients and promote safe medication use.

Pharmacovigilance is a continuous process, and new information about the safety of medicines is constantly emerging. By monitoring the safety of medicines and taking steps to mitigate risks, pharmacovigilance helps to ensure that patients have access to safe and effective medicines.

Pharmacovigilance Services:

- Audits
- Gap Analysis
- Inspection Readiness Activities
- Database Selection & Support
- Compliance Monitoring
- Development and Maintenance of the Pharmacovigilance System Master File (PSMF)
- System Implementation
- Maximization of Utilization
- Guidance in development of Patient Support Programs and Registries

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.

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.



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AUDITS | DATA MANAGEMENT | PHARMACOVIGILANCE | QUALITY MANAGEMENT | REMS