

METIS

Quality Assurance

Quality assurance (QA) provides the foundation and oversight in the Life Sciences industries, ensuring that products meet the highest standards of safety, efficacy, and consistency. Metis assists in the oversight of all aspects of product development, manufacturing, and distribution to prevent and identify defects, ensuring patient safety and regulatory compliance.

SERVICES

Design Control: review and approve product designs, ensuring regulatory requirements and quality standards are met.

Process Validation: ensure consistent production of high-quality products.

Material Testing: testing on raw materials, in-process materials, and finished products to ensure specifications are met

Environmental Monitoring: maintenance of optimal conditions for manufacturing environments to ensure product quality.

Document Control: Management of documentation related to product development, manufacturing, clinical and quality.

Auditing and Inspections: Assess compliance with procedures and identify areas for improvement.

Monitoring of Clinical Trial Activities: including site selection, investigator performance, and participant safety to ensure adherence to protocols and regulatory requirements.

Complaint Handling: Investigations and responses to product complaints to identify root causes and implement corrective actions.

Regulatory Compliance: Ensure compliance with regulatory requirements throughout the product lifecycle.

Risk Management: Identification, assessment, management and mitigation of risks associated with product development, clinical manufacturing, and distribution.

Continuous Improvement: Promotion of initiatives to enhance product quality and regulatory compliance.

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 bedside across all GxP functional areas. We help clients leverage cross-functional expertise to efficiently develop their assets while anticipating and proactively 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