

METIS

CONSULTING SERVICES

Audit, Gap Analysis & Inspection Readiness



Audit Services:

We take a systematic and structured approach to assess and verify compliance with regulatory requirements, quality standards, internal policies, and, in the case of vendors, contractual obligations. The audit process is critical for ensuring product safety, efficacy, and quality while meeting regulatory and quality standards. We use the audit findings and corrective actions as opportunities for continuous improvement.

Gap Analysis:

What is the difference between your organization's current practices and optimal conditions? Where are improvements needed to achieve efficiency, quality, and compliance with regulatory requirements? Do you need help identifying the roadmap for addressing deficiencies and achieving compliance to meet long-term goals? We can help. Our trusted advisors work with your current system to identify and plan for improvement.

Inspection Readiness:

The ultimate goal of any organization is to be inspection ready at all times. Health authorities expect that companies are always fully compliant with relevant guidelines and standards, including:

- Documentation
- Quality Control
- Facilities and Equipment
- Data Integrity
- Personnel Training
- Vendor and Supplier Oversight
- Quality Risk Management
- Communication and Training
- Corrective and Preventative Actions (CAPA)*

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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