Genomics & Analytical Services

GLP-Compliant Services

Good Laboratory Practice (GLP)-Compliant Services

Good Laboratory Practice (GLP) is a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are designed to support research for products regulated by government agencies. GLP is necessary at the final stage of preclinical development, at which point GLP documentation is needed for obtaining regulatory approval to continue development. GLP requirements are for non-clinical safety studies of drug development, agrochemicals, development of toxic chemicals, and food control.

When Do You Need GLP-Compliant Services?

For non-clinical laboratory studies in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety

- Animals
- Plants
- Microorganisms
- Subparts thereof

To Support FDA Applications

- IND
- ANDA
- NDA
- BLA
- 510K
- PMA

To Support EPA and EFSA Applications

Why Choose Azenta Life Sciences?

Our commitment to providing reliable, cost-effective services and high-quality results to top-tier pharmaceutical and biotechnology companies remain paramount in our GLP-compliant services. We treat all customer information, study-related data, and intellectual property, with the same degree of care and security that we do for our own. This allows all of our customers the flexibility to utilize our regulatory services while trusting in our commitment to quality and communication.

Features & Benefits

- A dedicated Study Director for proactive, transparent communication throughout your entire project.
- Rigorous planning, proven technology, and an outstanding quality management system gives you confidence that your project will meet FDA and EPA regulations.
- Project collaboration with scientific and quality assurance teams that includes a project-specific Study Protocol.
- Study Director-approved final Study Report.

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Azenta Life Sciences Services Offered

Confirmatory Sanger Sequencing

Provide your mammalian, insect, and prokaryotic cell banks, or your virus master stock and Azenta Life Sciences will design, develop, and/or optimize the assays to verify the bank's identity and stability of your samples.

Nucleic Acid

Azenta Life Sciences provides nucleic acid extraction as part of complete projects and as a standalone service. Simply provide Azenta Life Sciences with your sample and we do the rest.

SNP/Mutation Analysis

Azenta Life Sciences can sequence and analyze your clinical trial samples or confirm your diagnostic assay results per FDA and EPA GLP standards.

Plasmid Preparation

Azenta Life Sciences offers a range of DNA preparation services to accelerate research and preclinical development for customers in biotechnology, pharmaceutical, and other industries.

Deliverables

Azenta Life Sciences provides both electronic and hard-bound reports for easy incorporation into regulatory submission files. Components of customized final reports and data packages from Azenta Life Sciences may include, but are not limited to:

- Description of all materials and procedures
- Contig assemblies and graphic contig overview
- Consensus sequences
- Raw sequence data with accompanying quality scores
- GLP Compliance Statement signed by Study Director
- QAU Statement with inspection dates
- Detailed mutation report, where applicable
- Certificate of Analysis (COA), where applicable

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