GENEWIZ Quality System

Developed to support GENEWIZ operations, the GENEWIZ Quality System ensures that quality is built into all aspects of our services. For the customer, the GENEWIZ Quality System means strict regulatory adherence and consistency in all your data.

The GENEWIZ Quality System ensures quality through initiatives in design, assurance, and infrastructure.

Quality by Design

- GENEWIZ GLP-compliant laboratories in New Jersey
- Regulatory compliance and SOP training
- Method and Assay Validation procedures
- Customized Test Study Protocol Preparation and Reporting to each customer's requirements
- Vendor Qualification Program to ensure use of vendors that meet GENEWIZ Quality System standards

Quality by Assurance

- GENEWIZ Out of Specification (OOS) Investigation System: to investigate unexpected and abnormal results
- Corrective Action/Preventive Action (CAPA) System: to identify problem root cause and continuously improve quality
- Quality Trending System: to identify variations or trends in data
- Regular internal audits and management reviews

Quality by Infrastructure

- GENEWIZ Sample Handling and Tracking System: to control sample check-in, processing, storage, and disposal
- Laboratory with restricted access
- Installation, Operational, and Performance Qualification (IQ/OQ/PQ) Program all instruments used for GLP projects
- On-site fire-resistant data archiving
- Offsite data backup storage

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GENEWIZ

Trusted Partner for Regulatory-Compliant DNA Services

GLP / Regulatory-Compliant Services

DNA Sequencing
- Double strand sequence confirmation
- Primer walking
- Nucleic acid extraction
- Reverse transcription PCR and sequencing
- PCR amplification and sequencing

Plasmid Preparation
- Mini-to-giga scales
- Sequence confirmation
- Restriction enzyme digestion confirmation
- Endo-free options
- Custom Certificate of Analysis

GENEWIZ®
Solid science. Superior service.

Why GLP?

Plan now for future needs

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, agricultural pesticide development, development of toxic chemicals, and food control.

> “Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks … can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives, and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.”
>
> - Medicines and Healthcare products Regulatory Agency (MHRA)

GENEWIZ GLP DNA Sequencing and Plasmid Preparation Services

GENEWIZ provides GLP (regulatory submission) DNA sequencing and plasmid preparation services to the nation’s top pharmaceutical, biopharmaceutical, biotechnology and clinical institutions. You can expect Quality, Reliability, and Ease of Collaboration from our scientific and quality assurance teams ensuring that your project goals are fully met.

Services Include

DNA Sequencing Services	Plasmid Preparation Services
• Double strand sequence confirmation	• Mini-to-giga scales
• Primer walking	• Restriction enzyme digestion confirmation
• Nucleic acid extraction	• Sequence confirmation
• Reverse transcription PCR and sequencing	• Endo-free options
• PCR amplification and sequencing	• Custom Certificate of Analysis

Final Report and Deliverables

GENEWIZ will provide an electronic and a bound, written report that can be easily incorporated into your regulatory submission. The final report includes:

- Description of all utilized materials and procedures
- Contig assemblies and the graphic Contig overview
- Consensus sequences
- Details of the mutations and insertions/deletions detected, if applicable
- Raw sequence data with accompanying quality scores
- Certificate of analysis, if applicable
- Signed QAU Statement

All of our GLP DNA Sequencing Services provide at least 4-fold coverage of sequences of interest.

All GLP project-related documentation is archived for five years.

Do you need GLP level services?

GLP is a regulation. It is not only good scientific practice.

Our experienced PhD scientists can determine the appropriate level of regulatory oversight and requirements for your current project and future goals. Our familiarity with and understanding of regulatory requirements, research flexibility, pace, cost, and quality assurance ensures that you receive the level of services suitable for your project.

> “The needs of a discovery team are different from those of regulators. Whereas a discovery team is creative and flexible, regulators require such detail in the organization and documentation of protocols and processes. This can put undue burden on a discovery team.
>
> GENEWIZ can provide the necessary regulatory oversight for your study — allowing you to focus on your goals.”
>
> - Jeffrey Shaman, PhD, Study Director, GENEWIZ GLP Unit

How do you benefit from the GENEWIZ Experience?

We work with you and design a specific plan for your project that surpasses your expectations. We have decades of PhD-level research and development experience that is parlayed into the best strategy and execution of your project. We guide you through every step of the process so you can concentrate on your core responsibilities.

We have gained the trust and repeat business of large, international pharmaceutical companies and small biotechs alike through our dedication and:

- Technical consultation with dedicated PhD Study Director
- Fully customized services
- Validated SOPs, equipment, and facility
- Internal and client audits
- Computerized sample handling procedures to minimize human error

Quality by: Design, Assurance, Infrastructure

Audit
Customer requests an audit and visits GENEWIZ facility

Regulatory Compliance
From the moment samples arrive, your GLP project is GLP compliant and monitored by GENEWIZ Quality Assurance Unit

Documentation
Documentation complies with CFR 21. 58 and includes elements of cGMP compliance (21CFR211, 600, ICH Q7A). All GLP study-related data and documentations are archived for a period of five years in accordance with the regulations.

Final Report
The professionally-bound report is suitable for direct submission to the FDA and includes the signed Quality Assurance Statement confirming that all work was completed in accordance with Good Laboratory Practices.

Case Study

Regulatory DNA Sequencing to support Cell Bank Characterization for FDA submission

Client Profile
An international pharmaceutical, biopharmaceutical and medical device outsourcing company had a customer that was developing a biopharmaceutical agent. The company was characterizing Cell Banks for safety studies with the ultimate goal to move the studies through pre-clinical trials.

Business Needs
The company had a series of mammalian cell banks that needed GLP-level Cell Bank Characterization. As part of the requirements, confirmation of DNA identity and stability are required. The outsourcing company sought services that would return DNA and transcript sequences and documentation to comply with FDA regulations.

Technical Challenge
The company required the confirmation sequencing of transcripts from a stably transfected Master Cell Bank and an End of Production Cell Bank as well as the plasmid used in their development. The constructs had diverse structural characteristics that with conventional amplification and standard sequencing conditions would provide little usable sequence data.

GENEWIZ Solutions
GENEWIZ assigned a PhD Study Director to work directly with the client to assure that the project scope and requirements were understood. Through this individualized interaction and creative study design, GENEWIZ tailored a Study Protocol that fit the client’s intricate plasmid construct as well as their strict requirements of Quality Assurance and turnaround time. They chose to use one of GENEWIZ’s proprietary sequencing protocols to ensure high quality results. The great investment that GENEWIZ placed in its technology and Quality System assured that all of the client’s requirements were met in a timely, reliable manner.

Results
By working closely with the client, GENEWIZ designed a strategy that addressed the complexities in the original constructs and returned high quality sequencing data from multiple sources. GENEWIZ exceeded all of the client’s expectations in terms of ease of use, communication, quality, and turnaround time. The company has since submitted several projects due to the outstanding evaluation by their internal Quality Control Unit of the completed GENEWIZ Study Report.

GENEWIZ Management Process of GLP Regulated Services

Customer inquiry
↓
GENEWIZ assigns a dedicated, PhD Study Director
↓
Study Director consults with customer to understand Needs, Wants, and Goals
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Through individualized interaction, GENEWIZ tailors a Study Protocol that fits client’s needs
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GENEWIZ Quality Assurance Unit approves Study Protocol
↓
Client approves Study Protocol, sends sample(s)
↓
GENEWIZ GLP Unit receives samples and assigns unique identifier
↓
Project completed under FDA regulations described in CFR Title 21, Part 58
↓
GENEWIZ Quality Assurance Unit and Study Director ship signed Study Report