GLP/cGMP Regulatory-Compliant Services

Confidence through
compliance, collaboration,
and communication

GENEWIZ®
Solid science. Superior service.

GLP/cGMP Regulatory-Compliant Services

GENEWIZ provides Good Laboratory Practice (GLP) and current Good Manufacturing Practice (cGMP) regulatory-compliant services for FDA-level applications and submissions. High quality, reliability, and effortless collaboration with scientific and quality assurance teams, as well as commitment to excellence and consistent communication are just some of the advantages GENEWIZ offers.

Regulatory-compliant services available for FDA applications and submissions include RNA/DNA Identity and Stability Studies for: cell bank, plasmid, virus, and vaccine. Additional services include Single Nucleotide Polymorphism (SNP) testing, as well as DNA/RNA preparation for biomarker assays and validated internal controls.

GLP/cGMP Regulatory-Compliant Services

DNA Sequencing

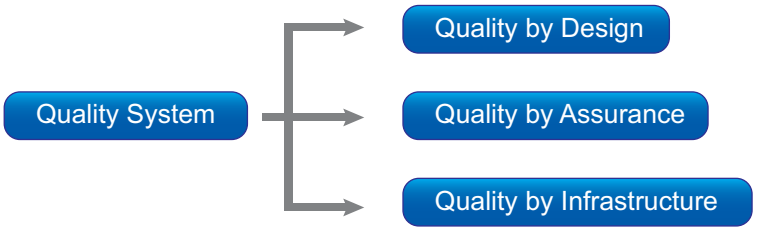
- Double strand sequence confirmation
- Primer walking
- Nucleic acid extraction
- Reverse transcription PCR and sequencing
- PCR amplification and sequencing
- Virus sequence confirmation

Plasmid Preparation

- Mini-to-giga scales
- Restriction enzyme digestion confirmation
- Sequence confirmation
- Endo-free options
- Custom Certificate of Analysis (COA)

GENEWIZ Quality System

The GENEWIZ quality philosophy ensures that quality is built into all aspects of our services. As a trusted partner for advancing research and product development, GENEWIZ constantly strives to meet the needs and expectations of our customers.



GENEWIZ GLP/cGMP Experience

GENEWIZ Value-Added Quality: Design, Assurance, Infrastructure

Audit	Regulatory Compliance	Documentation	Final Report
Customer requests audit and schedules GENEWIZ facility visit.	All Studies are compliant with GLP/cGMP regulations and monitored by GENEWIZ Quality Assurance immediately upon arrival at GENEWIZ.	In accordance with regulations, all Study documentation is compliant with 21 CFR 58, and all GLP/cGMP Study data and documentation are archived for a minimum of five years.	Custom reports are prepared in accordance with GLP regulations for easy, direct submission to the FDA.

Confidence in the GENEWIZ Experience

Through rigorous planning and proven methodology, GENEWIZ has gained the trust and repeat business of large, international pharmaceutical companies and smaller biotechnology companies alike. Together, we design a project-specific Study Protocol, including scope of work, SOPs, project requirements, and project deliverables. Both GENEWIZ and the project owner agree to and sign the Study Protocol prior to implementation.

The GENEWIZ experience includes:

- Customized services
- Technical consultation and follow-through with a project-dedicated Study Director
- Validated SOPs, equipment, and facility
- Internal and external audits
- Competitive pricing
- Elements of cGMP compliance (21CFR 211, 600, ICH Q7A) to support biopharmaceutical manufacturing Quality Control testing
- The GENEWIZ Quality System, developed in accordance with applicable FDA regulations described in Title 21, Part 58 of the Code of Federal Regulations for Good Laboratory Practice

Final Reports & Deliverables

GENEWIZ provides both electronic and hard-bound reports for easy incorporation into regulatory submission files.

Components of customized final reports from GENEWIZ include, but are not limited to:

- Description of all materials and procedures
- Contig assemblies and graphic Contig overview
- Consensus sequences
- Details of mutations and insertions/deletions detected
- Raw sequence data with accompanying quality scores
- Certificate of Analysis (COA)
- Signed QAU Statement

GENEWIZ GLP/cGMP Quality Process

GENEWIZ Commitment to High Quality & Expertise

The GENEWIZ Quality System and Management Process embrace our commitment to excellence and dedication to providing superior service.

Our mission to advance and accelerate life science research by providing reliable, cost-effective services and high-quality results remain paramount in our GLP/cGMP regulatory-compliant services. As such, GENEWIZ treats all customer information, Study-related data, and intellectual property with the same degree of care and security we do for our own. Transparent communication throughout your Study with your dedicated expert Study Director reinforces our commitment to your project's successful completion.

GENEWIZ GLP/cGMP Regulatory-Compliant Services Management Process

GENEWIZ Management Process commences upon receipt of Study inquiry

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GENEWIZ assigns dedicated Study Director

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Study Director consults with customer to clarify Study needs, goals, and objectives

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GENEWIZ develops custom Study Protocol to meet project-specific needs

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GENEWIZ Quality Assurance approves Study Protocol

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Customer approves Study Protocol

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Customer sends Study sample(s)

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GENEWIZ receives samples in an isolated Regulatory Services area, monitored by GENEWIZ QA

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Study completion is compliant with all applicable federal regulations

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GENEWIZ Quality Assurance and Study Director provide customized Final Report

Designed in accordance with the FDA Code of Federal Regulations (CFR), the GENEWIZ Quality System and Management Process are compliant with 21CFR 58 and 21CFR 211, 600, ICH Q7A.

Developed to support GENEWIZ operations, the GENEWIZ Quality System ensures quality throughout all aspects of our services. For customers, the GENEWIZ Quality System confirms strict regulatory adherence and consistency in all of your data.

The GENEWIZ Quality System enables high quality by design, assurance, and infrastructure.

Quality by Design

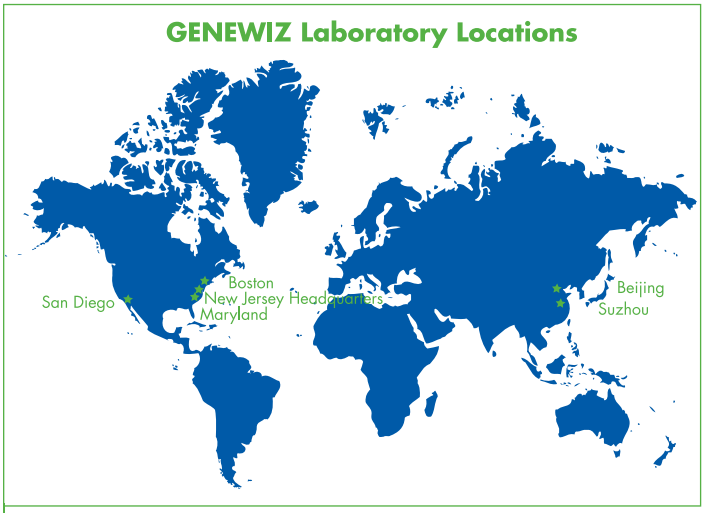
- GLP/cGMP regulatory-compliant laboratories
- Regulatory compliance and SOP education
- Method and Assay Validation procedures
- Custom Test Study Protocol Preparation and Reporting for your specific project requirements
- Vendor Qualification Program ensures all vendors meet GENEWIZ Quality System standards of excellence

Quality by Assurance

- Corrective Action/Preventive Action (CAPA) System: Identification of problem, the root cause, and continuous improvements in quality
- Out of Specification (OOS) Investigation System: Investigation of any unexpected and/or abnormal results
- Quality Trending System: Identification of variations or trends in data
- Regular internal audits and management reviews

Quality by Infrastructure

- Sample Handling and Tracking System: Controls sample check-in, processing, storage, and disposal
- Restricted-access laboratory compliant with GLP/cGMP regulations
- Installation, Operational, and Performance Qualification (IQ/OQ/PQ) Program: Qualifies all instruments used for GLP/cGMP projects
- On-site fire-resistant data archiving
- Off-site data backup storage



GENEWIZ Headquarters & Laboratory
115 Corporate Boulevard
South Plainfield, NJ 07080

GENEWIZ Boston Laboratory
19 Blackstone Street
Cambridge, MA 02139

GENEWIZ San Diego Laboratory
505 Coast Boulevard South
La Jolla, CA 92037

GENEWIZ Washington DC Metro Laboratory
20271 Goldenrod Lane
Germantown, MD 20876

GENEWIZ China Laboratories
Beijing
Suzhou

Sales & Support:
glp@genewiz.com
dnaseq@genewiz.com
1-908-222-0711 (voice)
1-908-333-4511 (fax)
1-877-GENEWIZ (toll free)

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