eurofins | Genomics

GLP

The Gold Standard For
Non-Clinical Safety Studies.

GLP CERTIFIED

Scope.

DNA sequencing services for registration or licensing purposes.

Good Laboratory Practices (GLP) defines the general guidelines for the conduct of non-clinical health and environmental safety studies for the following: drugs, pesticides, vaccines, gene therapeutics and genetically modified organisms (GMO) for the purpose of registering or licensing.

Meet the demands of regulatory authorities with GLP

The main focus of GLP is to ensure that test data is reliable, repeatable and auditable and is easily recognised by scientists and authorities worldwide.

Your benefits with GLP certified testings

- Full traceability of GLP study data
- GLP compliant archiving of study data and records
- Full compliance with GLP regulatory requirements (OECD, EMA, US-FDA, US-EPA)
- Acceptance of non-clinical safety study data by regulatory authorities in EU, US and worldwide

Key Requirements Of GLP Accreditation.

The requirements of GLP accreditation are similar to ISO 17025 with some additions:

- Test facility management (TFM)
- Study director (SD)
- Archivist
- Independent quality assurance unit and QA program
- GLP compliant study conduct and study inspection
- GLP compliant study documentation (protocol, report, SD and QA statements)
- GLP archive (archiving period >15 years)
- GLP training

GLP focuses strongly on the traceability and safety of the original test data (raw data) as well as clear responsibilities.

Compliance with GLP is achieved through certification by a national or state GLP authority and independent internal inspections (QA program).

The GLP standard is applied to the following Eurofins Genomics products and services offering:

- Custom DNA Sequencing
- Next Generation Sequencing

Applications.

Eurofins Genomics is committed to delivering products, services and applications that are at the highest quality.

Good Laboratory Practice is the highest QA standard Eurofins Genomics offers to their customers. If submission or registration to national authorities is necessary, then GLP compliance allows Eurofins Genomics to conduct non-clinical safety testing for the following applications:

Pharma & Diagnostics

- Pharmacogenetics & pharmacogenomics
- Assay development & validation
- Biological safety testing
- Genetic stability testing (GST)
- Diagnostic kit and device validation (for e.g. FDA and patent submissions)
- Analysis of production strains (inserted DNA, transcriptome)

Agriculture & Food

- Plant breeding
- Food production & retail
- Analysis of GM plants / food and feed for submission

Industrial Biotechnology

- Residual host cell and pathogen DNA & RNA analysis
- GMO & genetic insert characterisation,
- Basic genomic characterisation
- Metagenomic & genetic characterisation
- Microbial detection and differentiation

Quality Assurance.

Quality standards meet highest demands.

Discover a wide spectrum of DNA analytical products, services and applications that are compliant with globally recognised quality management (QM) and quality assurance (QA) standards.

Eurofins Genomics' products, services and applications reach the best quality and safety levels. They are carried out under strict QM and QA systems and comply with the following standards:

ISO 9001	Globally recognised as the standard quality management certification
ISO 17025	Accredited analytical excellence
ISO 13485	Oligonucleotides according to medical devices standard
GLP	The gold standard to conduct non-clinical safety studies
GCP	Pharmacogenomic services for clinical studies
cGMP	Products and testing according to pharma and biotech requirements

Contact Us.

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