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.

Toll free phone numbers

Austria	0800 296 562
Belgium	0800 77862
Denmark	8088 1262
Finland	0800 112 744
France	0800 903 807
Ireland	1800 555 056
Italy	800 785 950
Luxemburg	8002 6418
Netherlands	0800 0226215
Norway	800 138 44
Sweden	020 798 148
Switzerland	0800 562 013
UK	0800 0323 135

Email:
support-eu@eurofins.com

Phone:
+49 8092 8289-77

Official business hours:
8 a.m. – 6 p.m. CET

Eurofins Genomics · Anzinger Str. 7 a · 85560 Ebersberg · Germany
eurofinsgenomics.eu

2015_0102/07_2015/500

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GCP COMPLIANT

GCP
Focus On Clinical Studies & Patient Safety.

Scope.

Pharmacogenomic services for clinical studies.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials. They involve the participation of human subjects. When generating clinical trial data that is intended to be submitted to regulatory authorities (which is part of a drug registration or licensing), GCP guidelines must be adhered to.

GCP for strict guidelines on ethical aspects of clinical studies

The main focus of GCP is to ensure that the rights, safety and well-being of the trial subjects (humans) are protected according to the Declaration of Helsinki and that all clinical trial data are mutually accepted by regulatory authorities.

Your benefits with GCP compliant clinical studies

- Guaranteed confidentiality and integrity of clinical trial data
- Full protection of patient rights, safety and well-being
- Full compliance with GCP regulatory requirements (ICH, EMA, US-FDA, US-EPA)
- Acceptance of clinical study data by regulatory authorities in EU, US and worldwide

Key Requirements Of GCP Accreditation.

Overall requirements are similar to GLP. Any additional requirements are as follows:

- GCP specific trial conduct
- Patient safety
- Informed consent
- Blinding and unblinding, preparation and distribution of clinical kits
- Approval of all GCP studies by independent ethics commission

Compliance with GCP is ensured through customer audits and independent internal inspections (QA program). Certification of individual studies by national GCP authorities is possible, but not mandatory.

Applications.

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

GCP (Good Clinical Practice) is the basic QA standard Eurofins Genomics offers for the conduct of clinical trials. The following applications can be offered if submission or registration to national authorities is necessary:

Pharma & Diagnostics

- Pharmacogenetics & pharmacogenomics
- Conduct of clinical studies
- Genetic characerisation

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

- Genotyping & Gene Expression
- Custom DNA Sequencing