eurofins | Genomics

cGMP COMPLIANT

GMP

Safeguard The Patient's Health.

Scope.

Products and testing according to pharma industry standard.

Good Manufacturing Practice or GMP are practices and systems that are required to be adapted in pharmaceutical manufacturing, quality control (QC) and quality management systems (QMS). Covering the manufacture and testing of pharmaceuticals or drugs include active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products and medical devices.

The main objective of GMP is to safeguard the health of the patient, producing a high quality medicine, medical devices or active pharmaceutical products.

Safety for human consumption with the GMP standard

Your benefits with GMP certified products

- Full documentation and traceability of production processes
- Compliance with US and EU regulatory GMP requirements for production and quality control of medical devices (MD), in vitro diagnostics (IVD) or medicinal products

Key Requirements Of GMP Accreditation.

Overall the QM requirements are similar to ISO 13485 requirements. However, GMP includes several additions in regard to:

- Quality management
- Personnel, buildings and facilities
- Process equipment
- Production and process controls
- Management of complaints and recalls
- Packaging and identification labelling
- Storage and distribution
- Laboratory controls, validation and change control
- Risk and change management

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

Applications.

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

GMP is the highest achievable standard that Eurofins Genomics offers for production and 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)
- GMO and genetic insert characterisation
- Basic genomic characterisation
- Metagenomic and genetic characterisation
- Microbial detection and differentiation

The GMP standard is applied to the Eurofins Genomics service offering in the field of DNA & RNA oligonucleotides.

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

2015_0102/07_2015/500