

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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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.