GenoSafe*》*

Quality Control testing

750

DRUG SAMPLES ANALYZED EACH YEAR

Nearly

15

New tests validated each year according to ICH guidelines

OUALITY CONTROL

performed on any kind of batches: researchgrade,preclinical,clinical, and commercial batches

CUSTOMER BASE IN MORE THAN

COUNTRIES
(pharma,CMO,CDMO, academic institutions)

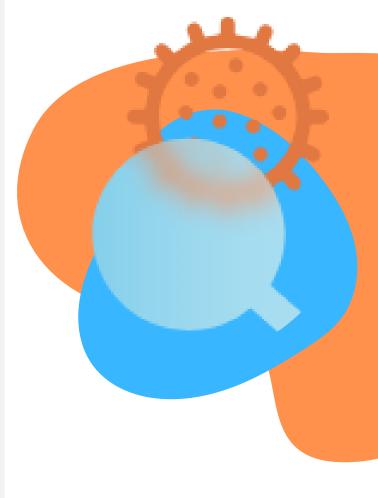
GenoSafe supports its customers by developing, validating and performing analytical methods in accordance with **ICH guidelines** and **GMP regulation**, to assess the different quality attributes of **innovative therapeutics** (safety, strength, identity, in vitro potency/efficacy and purity).

We offer several standardized test platforms and the development of tailoredmade tests, specific to your product.

GenoSafe helps you evolve in a complex and poorly standardized technical and regulatory environment.

We promote a flexible approach, tailored to your schedule, and an open communication with our customers

GenoSafe's services are used for **research**, **preclinical**, **clinical**, **and commercial batch release**.



Contact Us



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GenoSafe)



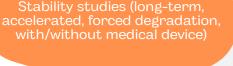
FOCUS 1 AAV Gene Therapy

- Infectious titration (TCID50)
- Viral genome titration (qPCR, dPCR)
- Physical titration (ELISA)
- Full/empty capsid ratio
- Impurity detection (residual plasmid DNA, DNA sizing, host cell DNA/proteins, antibiotics, BSA, other reagents)
- Replicative virus detection (rcAAV on any serotype of interest)
- Purity assessment (% VPI/VP2/VP3)
- Cell-based expression assays (RNA/protein)
- Potency assays

FOCUS 2

Lentiviral/Retroviral vector

- Infectious titration (infectious genome, cytometry)
- Physical titration (p24 ELISA)
- Impurity detection (residual plasmid DNA, DNA sizing, host cell DNA/proteins, antibiotics, BSA, other reagents)
- Replication competent lentivirus (RCL on product or producing cells)
- Replication competent retrovirus (RCR on product or producing cells)
- RNA/protein expression and quantification
- Cell-based assays (biological activity/potency)







FOCUS 3

Cell Therapy

GenoSafe offers tailor-made tests to assess the quality attributes of cell therapy products

- Cell counting and viability determination
- Cell characterization by cytometry (CAR expression, product purity, viability)
- Identity determination by qPCR (expression marker identification)
- Cytotoxicity test (T-cells, CAR T-cells)
- Potency tests, cytokine release
- CAR-T cell transduction efficacy (qPCR)
- Viral copy number (VCN) & replicative virus detection (RCL/rcAAV) on cell therapies derived from viral vectors