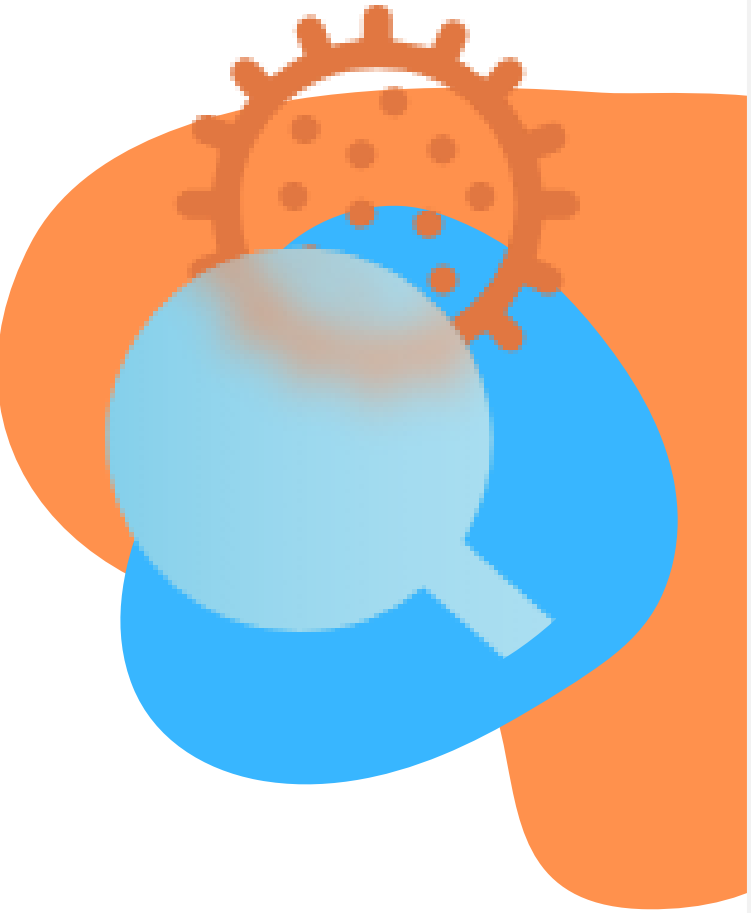

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GenoSafe supports its customers by developing, validating and performing analytical methods in accordance with **ICH guidelines** and **GMP regulations**, to assess the different quality attributes of **innovative therapeutics** (safety, strength,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

We offer standardized test platforms and capabilities for the development and validation of tailor-made 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**.

GenoSafe

Quality Control testing

750
DRUG SAMPLES ANALYZED EACH YEAR

15
new tests validated each year according to ICH guidelines

QUALITY CONTROL performed on research-grade, preclinical, clinical and commercial batches

A global customer base in more than **15** countries (pharma and biotech companies, CMOs, academic institutions)

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

Stability studies (long-term, accelerated, forced degradation, with/without medical device)

FOCUS 2
Lentiviral / Retroviral vectors

- 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 lentiviruses (RCL on product or producing cells)
- Replication competent retroviruses (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, viability and expansion
- Cell characterization by flow cytometry (CAR expression)
- Identity determination by RT-qPCR (RNA expression markers)
- Potency tests, cytokine release and cytotoxicity
- CAR-T cell transduction efficiency (qPCR)
- Vector copy number (VCN)
- Replicative virus detection (RCL/rcAAV) on cell therapies derived from viral vectors