

# GenoSafe

## Quality Control testing

**750**

DRUG SAMPLES  
ANALYZED EACH  
YEAR

Nearly

**15**

New tests validated  
each year according  
to ICH guidelines

QUALITY CONTROL  
performed on any kind  
of batches: research-  
grade, preclinical, clinical,  
and commercial batches

CUSTOMER BASE IN  
MORE THAN

**15**

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 tailored-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**.



## Contact Us



### Email

bd@genosafe.com



### Website

[www.genosafe.com](http://www.genosafe.com)



### Address

1 rue de l'Internationale/ BP40064/  
F-91002 Evry Courcouronnes/France



## 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 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