GenoSafe

Your analytical services expert

Evaluating advanced-therapy medicinal products

Preclinical studies :

- DNA/RNA Biodistribution/biodessimination analyses (from various tissues/fluids from different species)
- Gene and protein expression
- Immunogenicity studies
- Detection and quantification of biomarkers

GLP certified since **2008**

Involved in more than **40** preclinical studies overall

30,000 samples analyzed in 15 years

Quality control :

- Titration (physical/infectious titration)
- Identity (e.g. cell characterization, expression profile)
- Potency/expression assays (RNA/protein)
- Purity (residual DNA/protein)
- Safety (e.g. replication compentent viruses)

More than **750** drug samples analyzed each year

15 new tests validated each year according to ICH Q2 guidelines

An upcoming GMP facility expected in **2025**

Clinical bioanalyses :

- Shedding
- Gene and protein expression in biopsies
- Immunogenicity: neutralizing and anti-drug antibodies (titration, screening and confirmatory testing), and ELISpot assays
- Detection and quantification of biomarkers

Since 2015, **50** clinical studies in **35** different indications

10,000 clinical samples analyzed to date

90 validated methods including **15** generic methods

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