GenoSafe

Preclinical studies

GLP CERTIFIED SINCE
2008

INVOLVED IN MORE THAN
40
PRECLINICAL STUDIES OVERALL

90
EXTRACTION METHODS AVAILABLE FOR DIFFERENT TISSUES AND FLUIDS

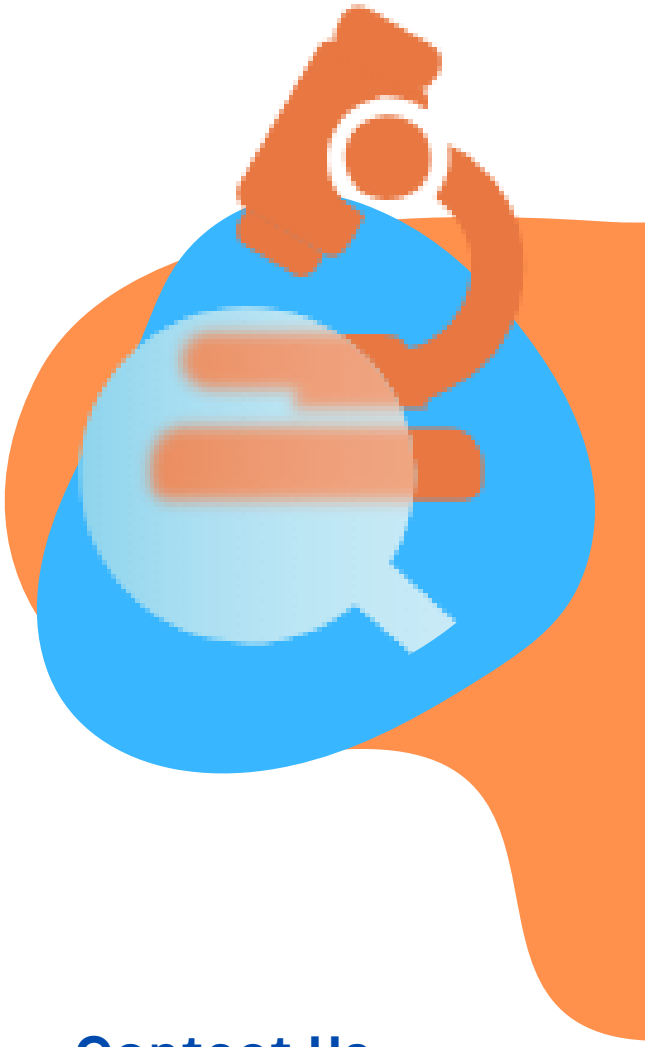
30,000
SAMPLES ANALYZED IN 15 YEARS

The objective of a preclinical evaluation is to demonstrate the in vivo proof of concept of a therapeutic approach and then determine the safety and efficacy of a drug candidate by assessing risks associated with their future use in humans.

GenoSafe supports its customers in the design, development, validation and implementation of the analytical methods used in this context, in particular to document the in vivo proof of concept, biodistribution / biodissemination and immunogenicity of a drug candidate.

Results generated in this context contribute to promote the transition to clinical trials and anticipate the adaptation of similar methods in humans. GenoSafe is GLP certified by the French Agency (ANSM) since 2008.

GLP



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GenoSafe

FOCUS 1

Characterization of the biodistribution / expression profile

GLP-Compliant Biodistribution / Expression analyses:

- Drug presence and persistence in animal samples
- Biodissemination to non-target tissues and fluids.
- Germline transmission and potential toxic effects, in combination with other preclinical safety indicators.

Our expertise includes:

- DNA/RNA extraction from various tissues.
- qPCR /dPCR /RT-qPCR for detection and quantification.
- Data analysis for biodistribution and expression profiling.

FOCUS 2

Immunogenicity assessment

Evaluating the immune response is a key step for preclinical development of biotherapies such as vaccines and gene/ cell therapies,

Through its expertise, GenoSafe conducts the following studies:

- Measurement of neutralizing factors/antibodies: Cell-based neutralization assays to quantify neutralizing factors/antibody titer, before and after treatment (e.g. AAV neutralizing antibodies)
- Detection of total/circulating antibodies: ELISA and MSD-ECLA assays for the quantification of antigen-specific antibodies.
- Evaluation of cellular immune response by ELISpot (Enzyme-Linked ImmunoSpot)
- Immune cell response profiling by flow cytometry

Several methods are already validated for certain species. GenoSafe can also develop, qualify, and validate custom assays per customers' requirements

Most immunogenicity tests are performed in compliance with Good Laboratory Practices (GLP).

FOCUS 3

Detection / Determination of Biomarkers

GenoSafe offers GLP-compliant biomarker analysis using ELISA and MSD-ECLA platforms,including

- Quantification of various biomarkers (cytokines, growth factors, cardiac biomarkers, complement factors, and any kind of biomarker of interest)
- Multiplexing analysis for simultaneous biomarker detection in small sample volumes