GenoSafe

Evaluating advanced-therapy medicinal products

GenoSafe is a full contract research and consulting organization which specializes in evaluating the quality, safety and efficacy of innovative biological products.

Choose GenoSafe

- **More than 10 years of experience**
- **A personalized approach**
- **Continuous innovation**
- **GLP and GCP compliance**
- **One-to-one support**
- **Reliable long-term partner**
- **European leader**

We provide a continuum of customized solutions all along the development of your product, from the proof of concept to market launch.

Our activities encompass 4 main domains of activities:

- Preclinical development
- Quality control testing – Product characterization
- Clinical development – Follow-up of subjects
- Regulatory affairs consulting

We advise and assist our clients in fulfilling their testing needs including the development steps that address challenges encountered during product development:

- Development and validation of specific assays and analytical methods
- Samples analysis

Placing our clients at the core of everything we do is our first priority.

The Company

GenoSafe

Preclinical

We provide support in designing studies in accordance with international guidelines. We perform the studies in full compliance with **GLP** regulations and provide detailed study reports to support regulatory submission.

Our main services for preclinical evaluation include biodistribution studies, gene expression analysis, protein analysis and immunogenicity assessment.

Quality control

We have unique expertise in the quality control of preclinical and clinical batches of viral vectors derived from adeno-associated virus (**AAV**) and **lentivirus**.

We foster a flexible approach and open communication with the product developer and manufacturer, whether based in Europe or in the USA.

Clinical

As specialists in the evaluation of ATMPs, we develop and implement specific assays for the evaluation and follow-up of subjects enrolled in clinical trials.

Our main services concern viral vector shedding and monitoring of immune responses. We meet **GCP** requirements.

Regulatory affairs

We implement specific regulatory approaches dealing with regulations and guidelines in conjunction with the characteristics of the product. We provide classification of biologics according to the European and North American regulations, and regulatory strategy advice for the development, manufacturing and control of **ATMPs**.

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