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Press Release

GenoSafe advances CLIA pathway for transatlantic ATMP development

- CLIA registration enables GenoSafe to support testing of samples from U.S.-based patients enrolled in clinical trials.
- This milestone strengthens GenoSafe's role as a transatlantic analytical partner for advanced therapy developers operating across the U.S. and Europe.
- One lab, one analytical approach, across two major clinical geographies.

Évry-Courcouronnes, France, May 19 – GenoSafe, a French Contract Research Organization (CRO) specialized in the analytical evaluation of advanced therapy medicinal products (ATMPs), today announces that its laboratory has obtained CLIA (Clinical Laboratory Improvement Amendments) registration certificate and number, enabling the company to begin testing clinical samples from U.S.-based patients enrolled in clinical trials. This milestone strengthens GenoSafe's ability to support sponsors conducting advanced therapy clinical trials across the United States and Europe by reducing operational fragmentation, improving analytical continuity, and supporting more consistent development strategies across regions.
The registration is part of GenoSafe's CLIA pathway, with full certification expected following an upcoming inspection by the College of American Pathologists (CAP).

"*This milestone is an important step in our ambition to support our US-based clients as well as our European customers as they expand their clinical programs in the United States*," said **Alain Lamproye, CEO of GenoSafe**. "*It allows us to simplify development strategies and ensure consistency in analytical approaches across regions*."

Enabling transatlantic clinical development

For European biotech companies, the analysis of clinical samples from U.S. trials has often required reliance on local laboratories, resulting in fragmented workflows and increased operational complexity.

With its CLIA Certificate of Registration, GenoSafe is now allowed to perform testing on human samples from U.S. clinical trials, enabling direct analytical support from its European facilities and ensuring continuity across development programs.
CLIA-registered laboratories remain limited in Europe, making this capability a strong differentiating asset in the ATMP CRO landscape.

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Supporting programs from early development to clinical stages

GenoSafe supports its partners across all stages of development, from preclinical research to clinical trials and quality control. Its services include analytical method development and validation, regulatory toxicology support, quality control testing, and clinical sample analysis, all performed in compliance with international regulatory standards (GLP, GMP, GCP).
GenoSafe offers both standardized, validated analytical methods and the ability to develop custom assays tailored to specific project needs. These capabilities can now be applied to U.S. clinical samples, strengthening its ability to support clinical programs across the US and Europe. This includes, for example, the quantification of neutralizing antibodies used to assess patient eligibility in gene and cell therapy trials.

About GenoSafe

GenoSafe is a French analytical CRO specialized in advanced therapy medicinal products, with recognized expertise in gene and cell therapies. The company provides analytical development, validation, and quality control testing services, all performed in compliance with international regulatory standards (GLP, GMP, GCP).
Founded in 2003 by Genethon and AFM-Telethon, GenoSafe supports innovative projects throughout all development phases and contributes to high-impact scientific and societal programs worldwide.
With a workforce of about 50, GenoSafe provides support to around 50 active clients worldwide each year.

🔗 https://genosafe.com/clia-registration/

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