Newsflash, June 2014

Regulatory Affairs

In addition to our traditional activities (analytical development, preclinical development, quality control testing and clinical development), we now offer consulting in regulatory affairs since the end of 2013.
Our consulting services include:
- Product classification according to the European and North American regulations
- Regulatory strategy advice for the development, manufacturing and control of ATMPs (Advanced Therapy medicinal Products) and other Biologics
- Administrative support such as registration as a SME with the EMA (European Medicines Agency), GMOs declarations according to the French regulation, biobanking declaration in France …

Collaborative project

GenoSafe is an industrial partner of European FP7-project NET4CGD. This project is focused on the clinical development of a new orphan drug that can rapidly become a new treatment option for patients with the X-linked form of chronic granulomatous disease (X-CGD).
In this project, we are particularly responsible for developing analytical methods, taking in charge quality controls of GMP-grade lentiviral vector batches, and following-up research subject included in the clinical trial.
More information

A new website

GenoSafe celebrates its 10th anniversary and launches a new website. With this website we offer an optimized access to our services and activities and enable the visitors to quickly find the information they are looking for.

Visit our website!