clean cells
SOLUTION FOR BIOLOGICS

EVALUATE THE GENETIC STABILITY OF YOUR CELL PRODUCT

Clean Cells offers an adaptable GMP compliant platform to assess the genetic stability of your cell based medicinal products. Since 2013 we have supported the approval of innovative therapeutic approaches by tailoring our investigation to the drug. We are able to understand gene behaviour in a cell following genetic modification or clonal selection. Critical for your CAR-T, CAR-NK and other modified lymphocytes, stem cells and new cell substrates, our services will guarantee the monitoring of your cells for safety and characterization purposes ensuring the success of your product development and approval.

A VALIDATED ASSAY TO SUPPORT GMP PRODUCTIONS COMPLIANT WITH:

- Eu. Phar. 5.2.3.
- USP (Chapter 1046: Cellular and tissue-based products & Chapter 1047: Gene therapy products).
- EMA: CHMP/410869/2006 & CAT/GTWP/671639/2008 & 319294/2010.
- FDA (CFR chapter §113.52).
- ICH Q5B & Q6D.

SAMPLE

You can deliver the sample as frozen vials, live cell culture or fixed cells:

- Unmodified/donor cells
- Modified cells from each step of development and production.

ASSAYS AND TECHNICAL APPROACH (GMP grade available for product release):

FEASIBILITY STUDY

- Setting up the custom criteria of our validated method to adapt to your cell product and define suitable specifications.

KARYOTYPING

- Structural aberrations (translocations, deletions, etc.)
- Numerical aberrations (trisomies, monosomies)
- Ploidy level abnormalities (haploidy, tetraploidy, etc.)
- Modal chromosome number
- Gross structural abnormalities (breaks, gaps, etc.)

FISH ANALYSIS

- To spot the target genes involved in an aberration
- To follow the evolution of a specific aberration

KARYOLOGY COUPLED WITH DIGITAL PCR

- Absolute quantification coupled with karyology to assess the accurate number of cells afflicted by a specific aberration.

a company of clean biologics
MAKING IT POSSIBLE

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