

# clean cells

SOLUTION FOR BIOLOGICS

## A CUSTOMIZED APPROACH

## TO DEVELOP, VALIDATE & PERFORM YOUR BIOASSAYS

Bioassays are essential for the determination of the biological activity or expression level of biologics. The availability of biologically-relevant and standardized assays is essential for regulatory compliance. Clean Cells is able to support you on specific development or transfer & validation of bioassays and to carry out them in GMP or R&D grade.



### WHICH BIOASSAYS FOR YOUR PRODUCTS?

- Monoclonal antibodies/Biosimilars/ADCs
  - Biological activity, potency assay,
  - Apoptosis induction,
  - Complement activation (CDC),
  - ADCC (antibody-dependant cellular cytotoxicity)...
- Advanced Therapy Medicinal Products
  - mRNA Expression level : Molecular biology tools: qPCR, dPCR,
  - Gene of interest expression assay,
  - Protein Expression level : immunochemical methods : ELISA,
  - Biological Activity : flow cytometry station,
  - Bioassay on cells and modified cells...

### STRONG EXPERTISE:

- In technics
  - Molecular biology
  - Immunochemical & biochemical methods
  - Flow cytometry station
  - Multimodal plate reader (fluorescence, luminescence...)
  - Patented method luminescence for Cytotoxicity measurement
- In design & development
  - Consulting, design, development, transfer, validation possible
  - Assay validation according to ICH Q2 & relevant guidelines
  - Qbd/DoE approach could be considered

### REGULATORY COMPLIANCE WITH:

- USP <1032>  
Design & development of biological assays
- USP <1033>  
Biological assay validation
- USP <1034>  
Analysis of biological assays
- ICH Q2

### YOUR BENEFITS:

- Expertise, Assistance & Solutions
- A customized assay from your needs/specifications
- A fully integrated in-house approach:  
manufacturing of cells, cell models available, design/  
development (or transfer) & validation of the assay,  
GMP routine testing
- Project follow-up & management

a company of  
**clean  
biologics**  
MAKING IT POSSIBLE

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