

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(R1) & 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 (R1)

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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