

clean cells

SOLUTION FOR BIOLOGICS

OUR SERVICES

Clean Cells is a GMP-licensed company dedicated to support the biopharmaceutical industry.

QUALITY CONTROL TESTING

According to Eur. Ph., US. Ph. and ICHQ5A guidelines

BIOSAFETY TESTING

- Sterility/Bioburden
- Mycoplasma test by qPCR or culture methods
- Non-specific Adventitious Agents detection (In-vivo, In-vitro)
- Specific Adventitious Agents detection via qPCR and RT-qPCR (Human, bovine, porcine, and other animals contaminants)
- Transmission Electron Microscopy (TEM)
- Retrovirus detection via infectivity and/or QPERT assay
- Replication-competent viruses: RCL, RCAAV

PURITY

- Residual Host Cell Protein (HCP) quantification
- Residual DNA testing
- Endotoxin testing
- Residual reagents quantification (BSA, benzonase)

IDENTITY

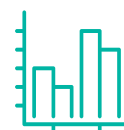
- Karyotype and FISH analysis
- Q-PCR-based species identification
- Genetic characterization of recombinant cell lines (gene copy number, vector copy number)
- Gene sequencing



DEVELOPMENT SERVICES

ANALYTICS

- Customized molecular biology (qPCR and digital PCR) and cell-based assays can be developed and/or validated (ICH Q2R1)



cGMP STARTING MATERIALS MANUFACTURING (one stop shop solution)

EUKARYOTIC CELL BANK

- Production of Master and Working Cell Bank, as well as generation of end of Production cells
- Adherent or suspension cell cultures
- Manual or automated filling/Controlled-rate freezing available
- BSL-2 environment, qualified area, Grade A in C
- Strict environmental monitoring and validated cleaning procedures

Cell banks track record :

Vero, CHO, HEK293, MRC-5, DF1, Human, Lymphocytes...

VIRAL SEED STOCK

- Production of MVSS and WVSS
- BSL-2 or BSL-3 environment
- Comprehensive QC testing panel available

Virus banks track record :

A wide expertise with a variety of viruses such as Vaccinia virus, Enterovirus, Coxsackievirus, Dengue, Rubella, Measles, Influenza virus, Adenovirus, Zika Virus, Epstein Barr Virus...



BIOASSAY

CYTOTOXICITY ASSAYS

- Innovative cytotoxicity potency assay, compliant with the Regulatory Authorities requirements
- In vitro assay for characterization of ADCC, CDC and/or apoptosis activities of the classical cytolytic antibodies
- Effector function: innovative standardized effector cell line or PBMCs
- Read-out: High-performance luminescence-based method or Chromium
- CAR-T: potency assays using the high-performance luminescence-based method

AN INNOVATIVE NON-RADIOACTIVE LUMINESCENT CYTOTOXICITY MEASUREMENT METHOD

- Specific of the target cell lysis triggered by cytotoxic antibodies
- Improved standardization potential via a reporter molecule
- Easy to implement via the use of widely available equipments (luminometers)



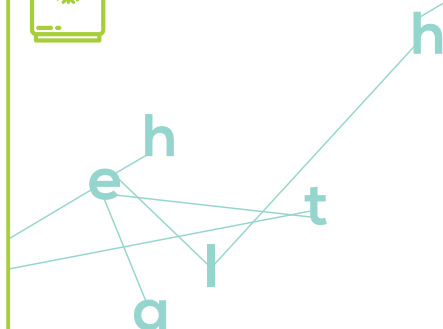
SPECIFICALLY DEVELOPED STANDARDIZED ADCC EFFECTOR CELLS

- Human cytotoxic T cells expressing Human CD16
- Absence of non-specific background lysis
- No inter-individual variability in ADCC response
- Intra-batch homogeneity
- Thaw-and-use format and long-term stability

STORAGE

STORAGE FOR R&D AND GMP PRODUCTS

- Qualified refrigerators (+5°C ± 3°C)
- Qualified freezers (-25°C ± 10°C / -80°C ± 20°C)
- Qualified cryocontainers (liquid or vapor nitrogen)
- Shared or dedicated storage
- Manual or semi-automatic filling
- Continuous temperature and nitrogen levels monitoring
- 24/7 externalized alarm system
- Restricted area



CLEAN BIOLOGICS' GROUP

VACCINE MANUFACTURING NEEDS ?

Our affiliate company **Naobios** offers a comprehensive set of services for process development and manufacturing of **viral vaccines and viral vectors products**.

This GMP certified CDMO could support you for the production of pre-clinical and clinical products assisted by Clean Cells for the quality control part.

• www.naobios.com



PROTEIN MANUFACTURING NEEDS ?

Our GMP certified affiliate company **Biodextris** can support you in process development, clinical batch manufacturing & characterization of your **therapeutic antibodies & recombinant proteins**.

• www.biodextris.com