

# clean cells

SOLUTION FOR BIOLOGICS

ONE STOP SHOP SOLUTION

FOR CELL BANK GENERATION AND CHARACTERIZATION

Clean Cells offers its expertise for manufacturing, release, characterization, and storage of a wide variety of mammalian, avian and insect cell banks. We propose production of GMP or non-GMP Master and Working cell banks, as well as generation of end of production cells in order to support your projects.



Cell banks are a key point in the development of biopharmaceutical products as they are used as starting materials<sup>(1)</sup> for various biologics. These cells banks need to be stable, robust and safe for further use.

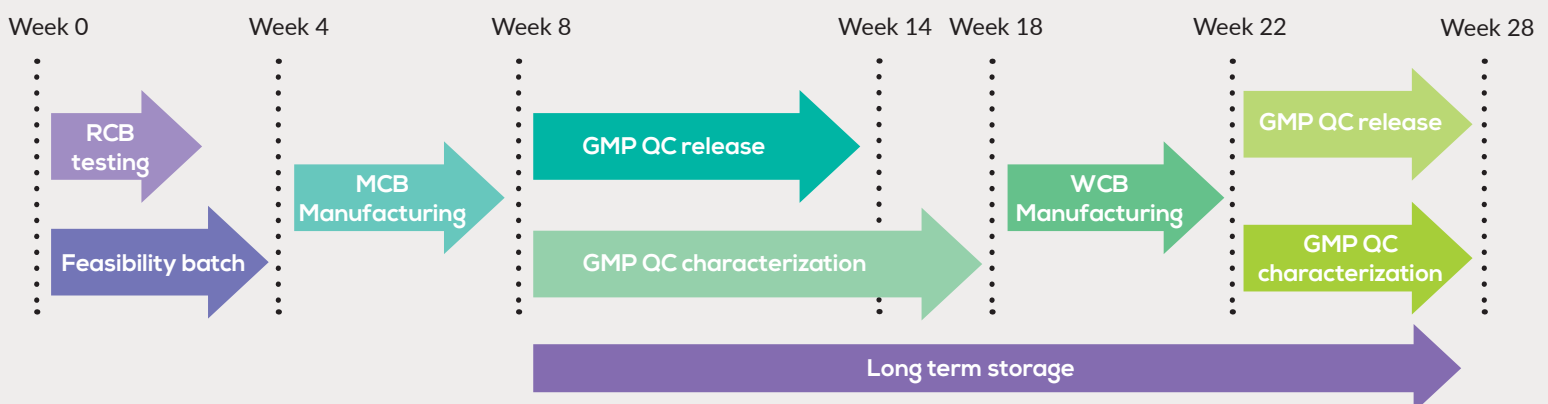
## ◦ STRONG EXPERTISE

Through our capabilities (5 GMP suites) and experience of over 20 years, Clean Cells offers a one-stop-shop solution for the production and characterization of your cell banks for human or veterinary health.



## ◦ OPTIMIZED PLANNING

As starting point of your clinical development, timelines for a complete cell banking generation and characterization are critical. As single-source solution, we propose an optimized planning based on your needs and your process.



*At the end of the feasibility step, vials of the feasibility batch can be available for our partner's process development.*

<sup>(1)</sup> Annex 1 and 2 of the current Eudralex - Volume 4 - Good Manufacturing Practice (GMP) guidelines

## OUR PROCESS



- GMP manufacturing according to Manufacturing files (Process & specification, Master Batch Record)
- BSL-2 environment, Qualified area, Grade A in grade C
- Environmental controls at the defined critical steps
- Equipment monitored continuously (temperature, CO<sup>2</sup> level, humidity)

QUALITY  
PROJECT MANAGEMENT  
QUALIFIED TEAM

## OUR TRACK RECORD



- **Non-GMP grade:** More than 500 cell models (human & animal)
- **GMP grade:** Vero, CHO, HEK293, SF9, Quail cells, DF-1, Human lymphocytes, MRC-5, leukemia cell lines, Hela cells...

EXPERTISE

## OUR TECHNOLOGIES



Suitable solutions for suspension and adherent cells

Static culture conditions:

- Flasks
- Multilayers

Shaking culture conditions:

- Spinner flasks
- Wave system
- Erlen flasks

Cell count using ViCell<sup>®</sup> or NucleoCounter<sup>®</sup>

FLEXIBILITY  
INNOVATION

## LONG TERM STORAGE OFFER



- Dedicated or shared qualified container
- Periodic storage report
- Continuous temperature monitoring
- Externalized alarm system
- Secured storage
- Backup containers

TRACEABILITY  
SECURITY

## CELL BANK CHARACTERIZATION SERVICES

According to Eur.Ph., US Ph., ICHQ5A and based on our partner's risk analysis:

- Sterility
- Mycoplasma
- Mycobacteria
- Non-specific Adventitious Agent Detection (In-vivo, in-vitro)
- Specific Adventitious Agent Detection (human, bovine, porcine and other animals)
- Retrovirus (electron microscopy, infectivity assays, qPERT)
- Identity
- Genetic Stability (Karyotype, Gene Copy Number,...)

END-TO-END SOLUTION