

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⁽¹⁾ for various biologics. These cells banks need to be stable, robust and safe for further use.

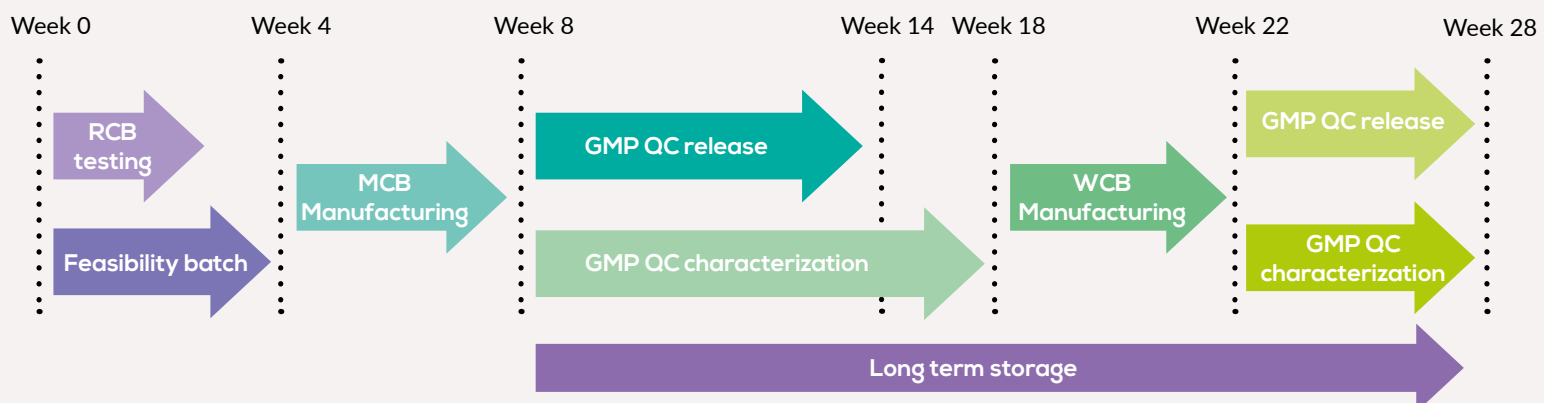
◦ STRONG EXPERTISE

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.

⁽¹⁾ 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, CO² 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[®] or NucleoCounter[®]

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