

| FEATURING |

## INTEGRATED SOLUTION FOR CELL BANKING & CHARACTERIZATION

Clean Cells, a GMP-licensed company, is a world-renowned expert providing **biosafety testing and characterization** services for all types of biopharmaceuticals since 2000. The company has also a **long-standing background providing manufacturing services** to generate starting material further used to produce vaccines, monoclonal antibodies, cell and gene therapies, and other biological products used in human and animal health.

Our expertise extends to cell banking: Clean Cells thus offers **a fully integrated solution for cell bank generation and characterization**. It is supported by countless partnerships around the world.

### Cell banks: a building block of biomanufacturing strategies

Biological products are complex and requires hands-on expertise to ensure that they meet the required **safety and stability** through **robust processes**. Cell banks (RCB, MCB, WCB) are essential building blocks of any bioprocess strategy and their quality often shapes the future of successful manufacturing projects.

With 20+ years of experience handling the most diverse cell lines, Clean Cells is at the forefront of the industry. We have worked with hundreds of cell lines including **mammalian, avian and insect substrates**.

Additional [virus banking services through our BSL2 and BSL3 capabilities](#) can be made available to sponsors leading virus-based manufacturing projects.

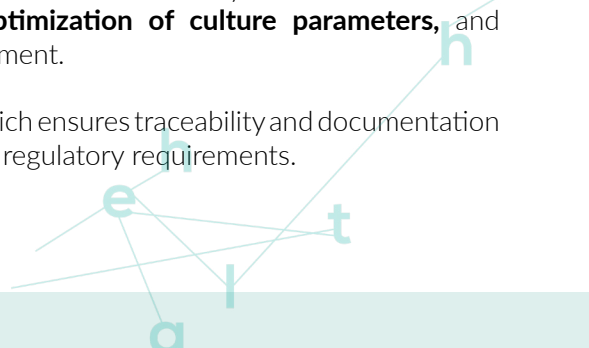
### 5 GMP suites for various suspension and adherence-based technologies



Our facility consists of **5 state-of-the-art GMP manufacturing suites**: the BSL2 grade A-in-C laboratories undergo environmental monitoring at critical steps while equipment is continuously monitored to prevent any defect and meet regulatory expectations. Equipment allows for **static cell culture** (flasks, multilayer for adherent cell lines) or **shaking cell culture** (spinner and erlen flasks, wave system for suspension cells).

Our cell banking services may be provided in **non-GMP or GMP environment** depending on the stage of your product and comes with fully **optimized planning** from initial RCB testing to cell bank release. An initial feasibility batch allows for the **proper method transfer from sponsor, optimization of culture parameters**, and provides starting material to process development.

Banking is supported by an **advanced QMS** which ensures traceability and documentation at each stage of production and according to regulatory requirements.



## Full characterization of cell banks

Cells banks are usually released through minimal testing and requires additional testing in a separate facility.

Clean Cells offers **a complete set of tests for the full characterization of cell banks according to GMP or non-GMP** requirements, thus building a one-stop-shop solutions for sponsors. Cell banks can undergo testing as soon as they become available internally: **timelines are optimized** and characterized banks can be used directly in your manufacturing process.

Characterization services include:

- 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,...)

A portfolio of 200+ assays in **biosafety**, **purity**, **identity** and **potency** is made available to sponsors in GMP or non-GMP settings and may be used in bespoke testing strategies.

## Long-term storage

Cell banks are valuable material and require secured storage to **ensure stability over time**.

Clean Cells offers **long-term storage services** for GMP and non-GMP bank preservation with the following specifications:

- Shared or dedicated storage
- Periodic storage report
- Continuous temperature monitoring
- Externalized alarm system
- Storage in a secured and separate area
- Backup containers



Please **reach out to the team** for additional information.

