BioReliance
Cell Banking and Storage

Cell bank development, characterization, and storage you can count on
To ensure the safety of biopharmaceutical products produced in living cells, global regulatory agencies require that cells used in the manufacture of these products be banked and characterized according to the highest possible standards. Who you choose to perform these tasks is critical to your ability to meet downstream development and manufacturing schedules. BioReliance’s cell banking services offer the confidence, convenience, and availability your unique bioproduction projects require and ultimately contributes to the overall success and achievement of your future goals. We have extensive experience banking mammalian and insect cells. From preliminary testing of seed stocks to preparing and qualifying cGMP Master and Working Cell Banks, to secure long term storage, BioReliance can meet your needs.

Comprehensive service, confident results
Our scientists are experts in cGMP cell bank production and cell line characterization. Biosafety testing and characterization methods include sterility and mycoplasma testing, C01 Barcode assay, in vitro and in vivo assays for adventitious viral contaminants, reverse transcription assays, antibody production assays, transmission electron microscopy, PCR and qPCR assays, bovine and porcine virus assays, and retroviral infectivity assays. A complete cell banking service, including pre- and post-bank testing, is generally completed in about four months (Figure 1, below).

Secure cell storage
BioReliance operates state-of-the-art, cGMP-compliant, controlled-access cell banking facilities both in the USA and the U.K. Both facilities are designed for short- and long-term storage of mammalian, insect and bacterial cell lines in liquid nitrogen vapor (LN2) or ultra cold (-80oC) freezers. Each bank to be stored is certified free from mycoplasma and tested for sterility prior to storage. Each bank is divided and stored in separate validated freezers. Bi-continental storage of cell banks is also available.

Figure 1. Timeline for a complete cell banking service.
Dedicated project team means no surprises
As part of our cell banking service, a dedicated project team will be assigned to you, to keep you informed of your bank’s production and testing progress on a regular basis. In addition to being available during the project, this knowledgeable team will consult with you in advance of production start to finalize technical specifications and testing in line with a compliant program.

Global facilities are available to complete your projects
Facilities for cGMP mammalian and insect cell banking are located in Rockville, MD and Glasgow, UK. Each facility has a continuous program for Materials Management and Control (MMC), QC and QA support for incoming raw materials processes, in process checks and cell bank certification as required to meet client needs. Our calibration and validation program, along with constant equipment monitoring, ensures that all equipment is maintained within specified process tolerances. All production areas are routinely cleaned and monitored to ensure that projects are carried out in a truly compliant environment.

Rockville, Maryland cGMP cell banking facility
The cGMP cell banking area consists of ISO 8 (class 100,000) entry and exit airlock, ISO 7 (class 10,000) process and return hallways, and functionally-independent ISO 7 processing suites. Each suite consists of 225 ft2 of operating space with terminally HEPA-filtered, 70% recirculated air under positive pressure from a dedicated air handler. All projects are antibiotic-free and handled in ISO 5 (class 100) laminar flow hoods with both static and dynamic environmental monitoring. Operator activities can be viewed from the outside by customers via telescoping cameras which zoom up to 32X and allow for documentation to be read from the monitor.

Glasgow, UK cGMP cell banking facility
The cGMP cell banking area consists of Grade B rooms, several dedicated to projects for single clients. The remaining cleanrooms are available for campaign use only. In Glasgow, all rooms are supplied by dedicated terminally HEPA filtered AHUs, all running on single pass air (100% fresh air, no re-circulation) under positive air pressure. Each cleanroom has a dedicated Grade D change area running at negative pressure to the corridor and the cleanroom to provide containment against adjacent areas. All aseptic processing takes place in Grade A biological safety cabinets with rooms and cabinets undergoing at rest and in process environmental monitoring in line with EU regulations.

Custom solutions
We recognize that every project has its unique characteristics. That’s why we provide every project with a custom plan of action. To learn more about BioReliance’s cell banking services or to discuss your project with an experienced representative, contact us at info@bioreliance.com today.