

Cell Banking and Storage

Cell bank development, characterization, and storage you can count on

BioReliance® cell banking professionals are experts at Cell Bank production for the biopharma industry. Our cGMP production facilities and extensive technical and regulatory expertise provide the support you need for efficient product development to achieve regulatory approval. Facilities for cGMP mammalian and insect cell banking are located in Rockville, Maryland, USA and Glasgow, Scotland, UK.

A master cell bank (MCB) is critical to therapeutic product development and supports not only clinical development and manufacturing but also the commercial supply phase for biologics. From the master cell bank, a working cell bank is produced to ensure high quality production and for scale up to manufacturing.

A working cell bank (WCB) is more commonly required at the later stages of therapeutic development and manufacturing. This bank is produced from a single vial of the MCB that has been grown for several passages and has been cryopreserved.

Successful cell banks include:

- Maintenance of a single master cell line
- Working cell banks with low passage numbers
- Identity confirmation testing, such as CO1 barcode assay
- Purity testing including mycoplasma, virus, and fungi detection
- Stability testing for expression constructs and viral vectors

In short, we ensure your precious cell lines are maintained for optimal production.

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, CO1 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).

Secure cell storage

Our state-of-the-art, cGMP-compliant, controlled-access biorepository facilities are designed for short- and long-term storage of mammalian, insect, and bacterial cell lines in liquid nitrogen vapor (LN2) or ultra cold (-80°C) 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.

- **Proven systems**
Cell banking since the early 1980s, with testing of over 1,000 banks
- **Cell bank experience**
Mammalian & insect cell lines
- **Full service**
Includes cell expansion, testing, and long-term storage
- **Global cGMP facilities**
Meet worldwide regulations, facilities in the US and Europe
- **Bi-continental cell storage**
Secure storage of eukaryotic, prokaryotic and viral biological materials

Related Services

- Biorepository
- Cell Line Characterization
- Genetic Stability
- Viral Clearance Services
- Lot Release Testing

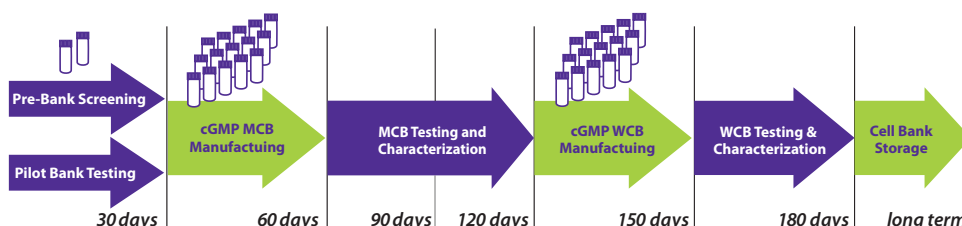
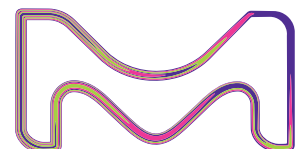


Figure 1. Timeline for a complete cell banking service.



Cell Banking and Storage

Global Facilities

16 cGMP dedicated cell banking suites globally meet worldwide regulations and provides flexibility.

Rockville, Maryland, USA

- Grade B (ISO 6, class 1,000) and Grade C (ISO 7, class 10,000) suites
- Non-clinical cGMP cell banking suite (i.e. cells for high quality cell based assays)
- Each suite consists of:
 - 225 ft² of operating space with terminally HEPA-filtered air
 - 70% recirculated air under positive pressure from a dedicated air handler
- All projects are antibiotic-free and handled in Grade A (ISO 5, class 100) laminar flow hoods with both static and dynamic environmental monitoring
- Operator activities can be viewed from the outside via telescoping cameras which zoom up to 32X and allow for documentation to be read from the monitor

Glasgow, Scotland, UK

- Grade B suites (ISO 6, class 1,000)
- All rooms are supplied by dedicated terminally HEPA filtered air handling units, all running on single pass air under positive air pressure
- Each cleanroom has a dedicated Grade D (ISO 8, class 100,000) change area running at negative pressure to the corridor and the cleanroom to provide containment against adjacent areas
- Aseptic processing takes place in Grade A (ISO 5, class 100) biological safety cabinets
- Able to perform viral and gene therapy cell bank production

Dedicated project team

As part of our overall cell banking service, a dedicated project team will be assigned to you. This team will be with you from start to finish; from consulting prior to production on finalizing the manufacturing specifications, providing progress updates during production, through completion of the regulatory compliant testing program.

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 our cell banking services or to discuss your project with an experienced representative, contact us at info@bioreliance.com today.

North America
800.553.5372
301.738.1000
info@bioreliance.com

Europe:
+44 (0)141 946 9999
info@bioreliance.com

India:
+91 (0) 22 6210 9000
indiainfo@bioreliance.com

Japan
+81 3 6758 3610
jpinfo@bioreliance.com

bioreliance.com

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada

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