

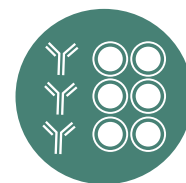


CELL BANKS FOR BIOASSAYS

Ensuring Long-Term Assay Reproducibility for Critical Reagents

DEDICATED, WELL-CHARACTERIZED ANALYTICAL CELL BANKS

Bioassay cells are considered critical reagents for implementation in lot release. Lot-to-lot reproducibility and consistent supply of the cells are some of the key factors that need to be addressed as part of the implementation process. Establishing a dedicated Master Cell Bank for manufacturing bioassay cells ensures a long-term supply of consistently-manufactured lots that deliver reproducible assays performance.

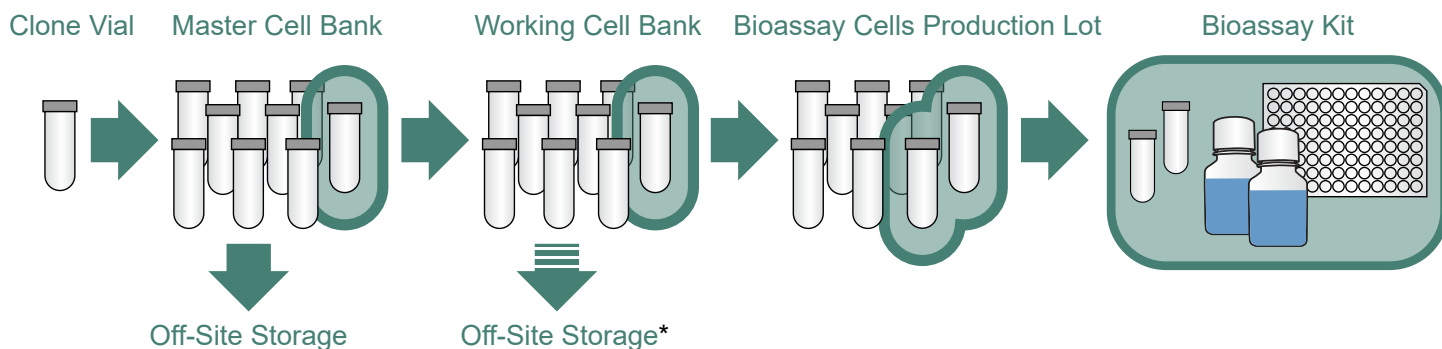


Confidently de-risk your biologics' lot release strategy by establishing a dedicated analytical cell banks for your bioassay.

Eurofins DiscoverX CELL BANKS FOR BIOASSAYS

- **Extensively Tested** – Well-characterized and QA-released banks to ensure long-term reproducibility for your bioassays implemented in lot release
- **Proven System** – Dedicated, two-tiered analytical cell banks for critical reagents (bioassay cells) supply assurance
- **Long-Term Storage** – Two-site secure storage to ensure continuous supply of bioassay cell for the lifetime of your therapeutic

WORKFLOW FOR CELL BANK MANUFACTURE TO BIOASSAY KIT DELIVERY



* Optional off-site storage for working cell bank (WCB) vials

Contact us at Projects_DRX@EurofinsUS.com to start your Cell Banks for Bioassays requirements discussion.

CELL BANKS FOR BIOASSAYS

Ensuring Long-Term Assay Reproducibility for Critical Reagents

CHARACTERIZATION & TESTING* OF CELLS

Clone	Master Cell Bank (MCB)	Working Cell Bank (WCB)	Bioassay Cells
<ul style="list-style-type: none">• Cell Line Identity & Purity• Passage Stability• Sterility & Mycoplasma Testing	<ul style="list-style-type: none">• Functional Performance• Passage Stability• Sterility & Mycoplasma Testing	<ul style="list-style-type: none">• Functional Performance• Sterility & Mycoplasma Testing	<ul style="list-style-type: none">• Functional Performance Bioassay QC• Sterility & Mycoplasma Testing

* Optional cell testing: Viral and bacterial pathogens, cell line identity, compendial mycoplasma testing, and direct inoculation sterility testing available upon request.

CELL BANKS FOR BIOASSAYS PROJECT PROCESS & DELIVERABLES

Phase

1

Define Analytical Cell Bank Requirements

- **In-Depth Consultation** – Detailed discussions with our bioassay experts to review and define your specific requirements
- **Defined Deliverables** – Detailed work plan with timelines, bank deliverables, and project pricing
- **Additional Options** – Define additional testing requirements (compendial methods) and cell bank options (e.g. additional vials or storage sites) to meet your development program requirements

Phase

2

Cell Bank Manufacture and Characterization

MCB Generation

- Production, characterization and testing of MCB to ensure reproducible assay performance
- Certificate of Analysis issued for the QA-released MCB

WCB Generation

- Production of WCB from MCB vial, and testing to establish as raw material for manufacturing ready to use bioassay cells
- Certificate of Analysis issued for the QA-released WCB

Phase

3

Bioassay Cells Production and Bank Storage

- **Cryopreserved Cells** – Bank Cells stored and maintained at constant, ultra-low temperatures to increase longevity
- **Split Sites Storage** – MCB vials are maintained at two separate locations; Fremont, CA production site and a secure, controlled and monitored out-of-state storage facility
- **Documentation** – Detailed data available upon request

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