

GMP-Grade Mammalian Cell Banking and Biorepository

Compliance | Safe | Controllable | Reliable

GMP

ISO

ICH

- Strictly following cGMP and ISO 9001 quality system, complying with requirements in ChP , USP, EP, ICH Q5D and WHO
- MVE HEco™ 800 high efficiency vapor-phase liquid nitrogen system: preventing cell contamination and ensuring the safety and integrity of cell banks
- Strict environmental monitoring system (EMS) ensures long-term biorepository in a highly stable environment
- Cell bank storage capacity of up to ~200,000 cells
- Scientific project management system to reduce the project lead time

BRC Biotech GMP-Grade Biorepository Service

BRC Biotech cGMP integrated the advantages of the facility standards, professional technology and compliant management system to ensure your cell banks in a safe and controlled environment, providing efficient supports for your product development and production.



cGMP CNC follows good management norms

- Authorization to manage biorepository
- Vapor Phase Liquid Nitrogen System
- Separated released and unreleased areas
- Store MCB and WCB in separated containers
- Unique ID code for locations recording
- Strict data security system

MVE HEco™ 800 High Efficiency Vapor Phase Liquid Nitrogen System

- Compliance with cGMP validation
- Compliance with 21CFR Part11 data recording and tracking
- Safe and controlled biorepository
- Avoid cross contamination by liquid nitrogen
- Strict environmental monitoring system
- Real-time temperature monitoring and recording

Strict adherence to global standards and national legislations

- Pharmacopoeia of the People's Republic of China 2020 Edition
- ICH Q5D
- WHO
- FDA 2010
- EP 5.2.3



World Health Organization



ICH
harmonisation for better health



BRC Biotech GMP-Grade Cell Banking Service



- Four cell banking facilities
- Two GMP C grade facilities (BSL-2)
- Two GMP D grade facilities (BSL-2)
- Area Space
- ✓ Cell banking facility 1 (D-level) : 34.19m², Cell banking facility 2 (D-level) : 37.59m²
- ✓ Cell banking facility 3 (C-level) : 40.97m², Cell banking facility 4 (C-level) : 27.99m²
- HEPA air filtration
- Air change system
- Antibiotic-free operating conditions
- Six-foot class A biological safety cabinet
- Static and dynamic environmental monitoring
- Autoclavable CO₂ incubation system

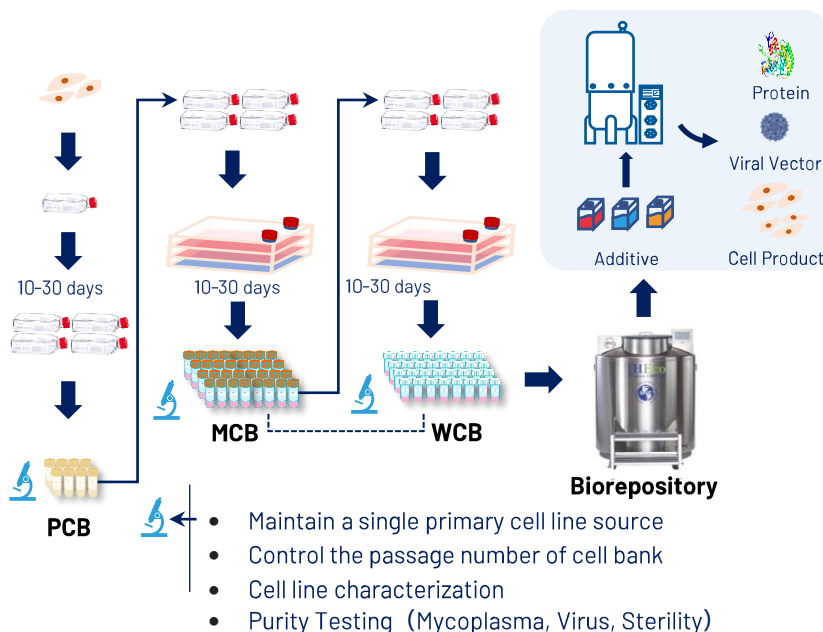


Scientific project management system

1. Dedicated project team
2. Clear management norms for samples
3. Project document management

Cell Bank Related Services Customized Solution

- ✓ Cell Line Characterization
- ✓ Purity Testing
- ✓ Adventitious Virus Screen
- ✓ HCD Distribution Analysis
- ✓ Raw Material Testing
- ✓ Batch Release Testing
- ✓ Protein Conc Determination
- ✓ Genetic Stability
- ✓



CONSULTATION



400-178-2022 | info@brcgroup.cn | www.brcgroup.cn

Building 3, Simbay Park, No.160 Basheng Road, Free-trade Zone | Shanghai | China



For technical support and ordering inquiries, please contact via **400-178-2022**, we provide you with 7 X 24 hour online support!