

# BioReliance

## Cell Storage Services

### Introduction

Many biopharmaceutical organizations - whether from the private or public sector - invest significant resources to create stocks of biological reagents, valuable cell lines and other stocks, yet they fail to set aside a portion of their lots for long-term storage at a site removed from their primary storage area. The International Conference on Harmonization (ICH) recommends that manufacturers carefully consider the steps that can be taken to provide protection from catastrophic events that could render cell banks unusable, such as storage of a portion of the master cell bank (MCB) and working cell bank (WCB) at remote sites.

In order to meet the need for secure, long-term storage of cell banks, BioReliance has developed the capacity to provide long-term storage for our clients' biological reserves that are simply too valuable to risk losing.



### Why choose BioReliance?

At BioReliance, we know that the safety and security of your cell banks are your highest priority, so we have made it ours. For over eight years BioReliance has been storing eukaryotic cell lines under current Good Manufacturing Practices (cGMP) in our biorepository to ensure that when they are needed, they are available. BioReliance has incorporated a number of practices that keep risk to a minimum when it comes to counting on long term reserves.

#### ■ Secure Cell Storage Services

Our 2,500 square foot US facility is monitored 24 hours a day, seven days per week. Our cGMP liquid nitrogen freezers provide a secure storage environment that maintains temperatures below  $-150^{\circ}\text{C}$ . In accordance with recommendations from the Centers for Disease Control and Prevention (CDC), the samples are stored in the vapor phase of liquid nitrogen.

#### ■ Safety Precautions

Before any cell bank is placed in our freezers, it must be certified as being free from mycoplasma and tested for sterility. As an added precaution, when your cell banks are received, each bank is divided equally and stored in separate liquid nitrogen freezers so that in the rare event of a complete freezer malfunction, a second grouping of vials is still available for subsequent use.

#### ■ Monitoring Systems

Liquid nitrogen levels and freezer temperatures are monitored with redundant monitoring systems 24 hours per day. Each working day liquid nitrogen levels are monitored manually to corroborate electronic reading. In the unlikely event of a power interruption, a natural gas powered backup generator will ensure that our freezers continue to maintain temperature, without interruption.

## ■ Security Controlled

Access to our facility is tightly controlled and only trained BioReliance staff have access to the biorepository storage area.

## ■ Alarm Response

Alarms are tested on a weekly basis to ensure that an optimum environment for your cells is maintained. Our staff are on call 24 hours a day.

These are only some of the features that allow us to give our clients the confidence they require for their long-term valuable reserves. In addition, we offer discount pricing for smaller banks which allows reserves to be held on many cell banks or different lots at very affordable rates.

## ■ Cell Bank Services offered by BioReliance

### CELL STORAGE

Cell storage agreements are available on an annual or multi-year basis. You may retrieve your cell banks at anytime, and should you require that your bank or any number of vials be sent to a third party, BioReliance can make all of your arrangements.

### STERILITY & MYCOPLASMA

Contamination of cell banks and unprocessed bulk by bacteria, fungi and mycoplasma is a potential risk in the production of biotherapeutics. At BioReliance we require that all cell banks are free from mycoplasma and have been sterility tested. We require that your company provide us with a written guarantee that these tests have been performed. Should you require assistance with this testing, BioReliance can perform testing on-site as part of our regular services available to clients.

### CELL BANK & MANUFACTURING

BioReliance's global manufacturing centers focus on the production of virus-based therapeutics, cell therapies, eukaryotic and prokaryotic cell banks and microbial fermentation. If your company would like assistance in generating cell banks, we can produce your master or working cell bank under cGMP conditions at our facility.

### CELL LINE & CHARACTERIZATION

BioReliance offers a complete testing program to characterize cell banks, covering identity and homogeneity, purity, and suitability for use, helping to ensure the safety and efficacy of human biologics. Our expert scientific teams remain accessible to you at all times, from study design to beyond the final report.

BioReliance has extensive experience of biological sample storage and handling, offering long-term storage services for a wide variety of biological materials and chemicals. These can also be used in partnership with our cell banking and characterization services. If your organization has a need for high quality and secure off-site storage then please let us know and we will work with you to provide a customized solution for your needs.

**Come to BioReliance and let us provide you with  
secure, long-term storage of your biological materials.**



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