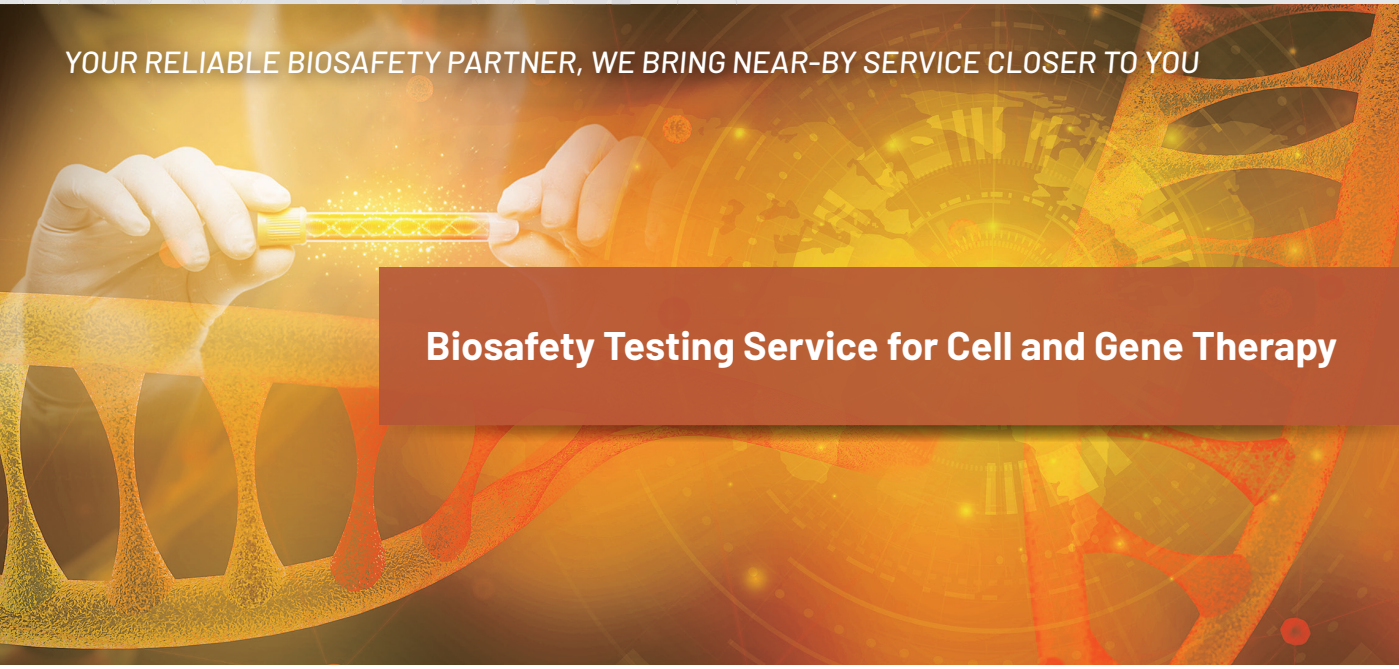
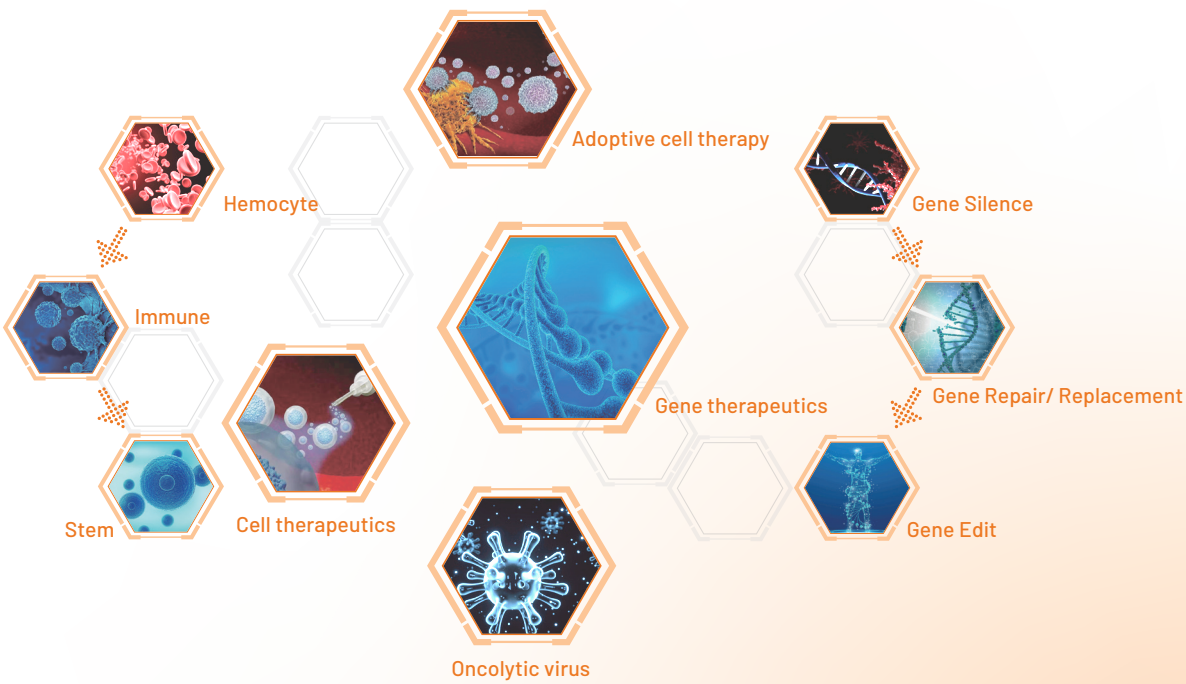
*YOUR RELIABLE BIOSAFETY PARTNER, WE BRING NEAR-BY SERVICE CLOSER TO YOU*



# Biosafety Testing Service for Cell and Gene Therapy

Cell & gene therapy has been significantly developing in the treatment of tumor, autoimmune diseases, rare diseases and epidemic prevention. As highly innovative products, biosafety control is more critically required in cell and gene therapy. Compliant testing technology is efficiency solution to ensure drug safety in the development and production of cell and gene therapy products.

BRC Bio is committed to providing professional, compliant and efficient biosafety testing services for all cell and gene therapy products.

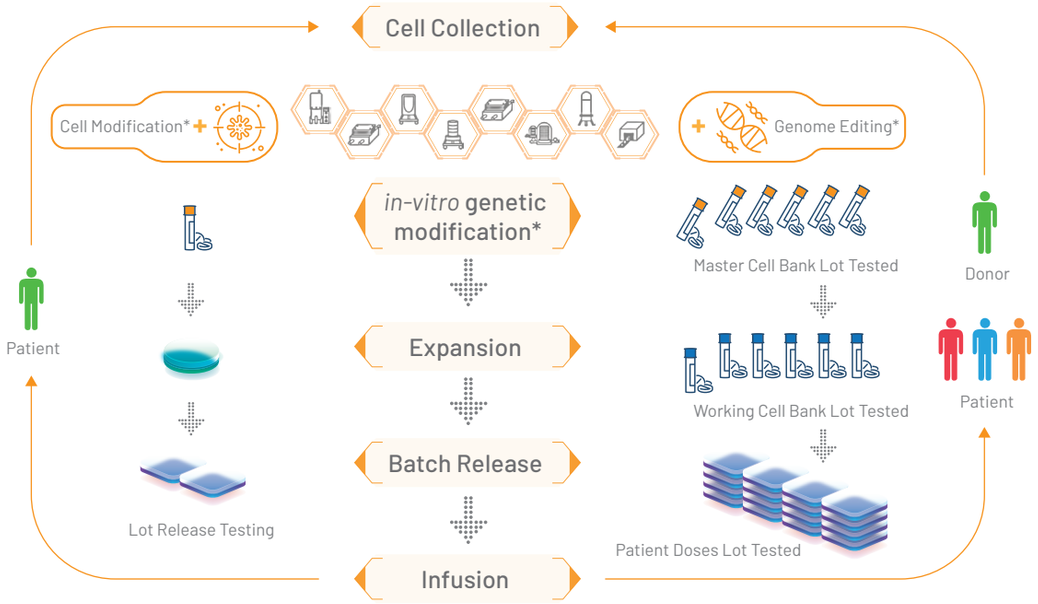


## Cell Therapy

By modifying autologous/allogeneic cells, cell therapy products can be feasible for organization damage repair, tumor killing, immune reconstruction etc. Currently, cell therapy is maturing and becoming the high hot zone in the pharmaceutical industry. Development and manufacture technologies of cell therapy is focused globally, while the safety consideration is developing rapidly.

BRC Bio is providing the service in cGMP+BSL2 environment and meeting the global regulatory compliance.

- √ Autologous/Allogeneic Cell Characterization
- √ Allogeneic Cell Banking And Donor Testing
- √ in vitro Human Pathogens Screening
- √ in vitro Human Pathogens Specific Testing
- √ Product Characterization of Modified Cell




Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs). FDA, 2008
Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs). FDA, 2020

Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products (For comments). FDA, 2022


**Product**
- √ Viral Vector

**Auxiliary Material**
- √ Plasmid
- √ Viral Seed
- √ Impurity
- √ Host Nucleoid Acid
- √ Host Protein
- √ Bacteria/Fungi
- √ Mycoplasma
- √ Adventitious Virus
- √ Transit Transfection Reagent
- √ Nuclease

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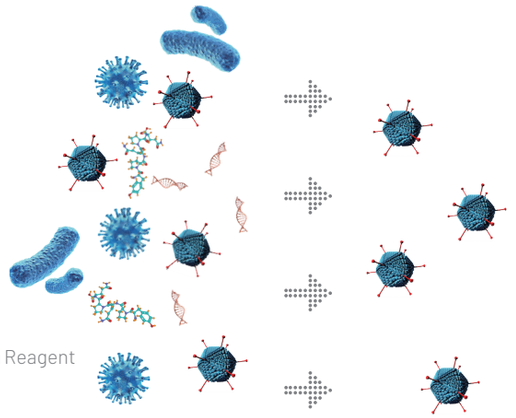


**Product**
- √ Viral Vector

Viral Vector Identity

Viral Vector Characterization

Impurity Detection

Impurity Determination Quantitatively

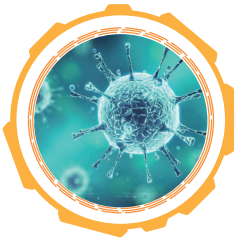
## Gene Therapy

Gene therapy start a new era of treatment in rare diseases. Engineered viral vectors is the major product format of gene therapy products currently. Its complex production process and critical quality standards is original from the high technical and safety requirement of gene therapy products.

BRC Bio is providing the service in cGMP+BSL2 environment and meeting the regulatory requirements from FDA, EMA, WHO and ChP.

- √ Host Cell Banking
- √ Cell Line Characterization
- √ Viral Seed Banking and Characterization
- √ Identity of Gene Therapy Product
- √ Testing of Gene Therapy Product
- √ Raw Material Testing
- √ Rapid Detection Solution Development


A FAITHFUL PARTNER TO HELP YOU WITH DRUG SAFETY TESTING

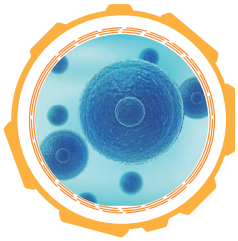


## Target Development and Validation

- HiMice Immune System Humanized Mice
- HiMice Immune and Liver Dual Humanized Mice

## Cell Banking

- GMP-grade Cell Banking



## Biorepository

- GMP-grade Biorepository

## Cell Line Characterization

- Cell Original Analysis
- Cell Line Identity
- Sterility Testing
- Mycoplasma Testing
- Mycobacterium Testing
- DNA Residual Detection
- *in vivo*/*in vitro* Adventitious Virus Detection
- Rapid Species-specific Virus Detection
- Retrovirus Detection
- Genetic Stability Analysis

## Viral Vector Characterization

- Sterility Testing
- Mycoplasma Testing
- Endotoxin Detection
- DNA Residual Detection
- Viral Vector Identity
- Gene of Interest Identity
- Infective Titer Determination
- Genomic Titer Determination
- Nuclease Residual Testing
- Host Genome Residual Determination
- Host Protein Residual Determination
- Replication-competent Virus Detection

## Modified Cell/Stem Cell Product Testing

- Rapid Sterility Testing
- Rapid Mycoplasma Testing
- Rapid Mycobacterium Testing
- Rapid Replication-competent Virus Detection
- DNA Residual Testing
- Size Distribution Analysis of Residual Nucleoid Acid

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