



# **One-stop CDMO-Plus Service Provider for CGT**



## Grade C+A

- ✓ Grade A / ISO 5 completely enclosed isolators
- ✓ Grade C cleanrooms
- ✓ Individual HVAC systems



## Scalable platform capabilities

- ✓ 10+ years of experience in CGT field for core team members
- ✓ Plasmid scales: 10L, 50L, 200L
- ✓ Mammalian cell scale **200L, 500L, 2000L**



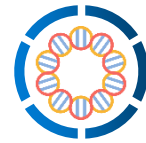
## Cost effective processes, shorter cycle

- ✓ Six advanced technical platforms, 60+ viral vector and 100+ GMP CAR-T batches produced
- ✓ Advanced two-step chromatography purification process, high recovery rate, lower cost
- ✓ Multiple QC methods for cross reference, strict quality standards for all platforms



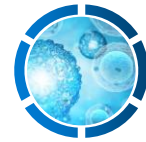


## Platforms



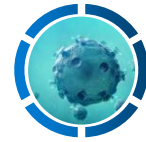
### Plasmids

- ◆ Plasmid construction
- ◆ Strain banking
- ◆ Plasmid PD & manufacturing



### Cell therapy

- ◆ CAR-T, TCR-T
- ◆ CAR-NK
- ◆ MSC, iPSC, cell banking



### Viral Vectors

- ◆ LVV, RVV
- ◆ AAV
- ◆ Adenovirus
- ◆ OV



### Gene Editing

- ◆ IVT-sgRNA
- ◆ Nuclease
- ◆ RNP PD



### RNA-LNP

- ◆ mRNA
- ◆ circRNA, saRNA
- ◆ IVT-sgRNA



### QC release testing

- ◆ Safety
- ◆ Identity
- ◆ Potency

## GMP Plasmid



- ✓ **High fermentation yield of >1g/L; fermentation scale up to 200L**
- ✓ **No antibiotics or animal-derived ingredients**
- ✓ **Innovative and efficient two-step chromatography**
- ✓ **FDA-recognized drug master files of AAV and lentivirus helper plasmids**

## GMP AAV



- ✓ **293XS suspension cell culture**
- ✓ **Cell culture scale up: 200L – 500L and high yield: 1E14VG/L**
- ✓ **Helper plasmids received DMF confirmation from the FDA, streamlining IND package**
- ✓ **High full/empty ratio: 96% full capsids after UC**
- ✓ **Fully developed purification platform for various serotypes: rAAV2, rAAV5, rAAV8, and rAAV9**

## GMP LVV



- ✓ **Multiple cell culturing process: cell factory (293T), suspension culture (293TH),**
- ✓ **Helper plasmids received DMF confirmation from the FDA, streamlining IND package.**
- ✓ **Cryopreservation Formulation: Improving Lentivirus Stability**

## CAR-T, CAR-NK, iPSC



- ✓ **CAR-T: Access to lentivirus production with 100+ CAR-T cases**
- ✓ **iPSC**
  - iPSC cell bank
  - iPSC reprogramming mRNA-LNP cocktail
  - iPSC generation services

## RNA Manufacturing and Products



- ✓ **Integrated CDMO services**
  - Including plasmid, RNA manufacturing, QC testing, and regulatory filing
- ✓ **Versatile RNA platforms: mRNA, circRNA, saRNA**
- ✓ **Microfluidic technology for RNA-LNP preparation, >90% encapsulation**

## CRISPR Gene Editing Services & Products



- ✓ **GMP Cas9 proteins, mRNA**
- ✓ **RNP formulation services**
- ✓ **sgRNA in vitro transcription**
  - Scalable & cost-effective
  - Reduced timeline
- ✓ **Donor DNA production**
  - Linear DNA closed end

## FDA-regulated Ph1 study:

- 10 patient trial
- 24-48 months
- \$30-50M for CGT Ph1 Study

## uBriGene-coordinated Chinese IIT:

- 10 patient trial
- 12-18 months
- <\$5M for CGT IIT Study

## Benefits of uBriGene-coordinated Chinese IIT:

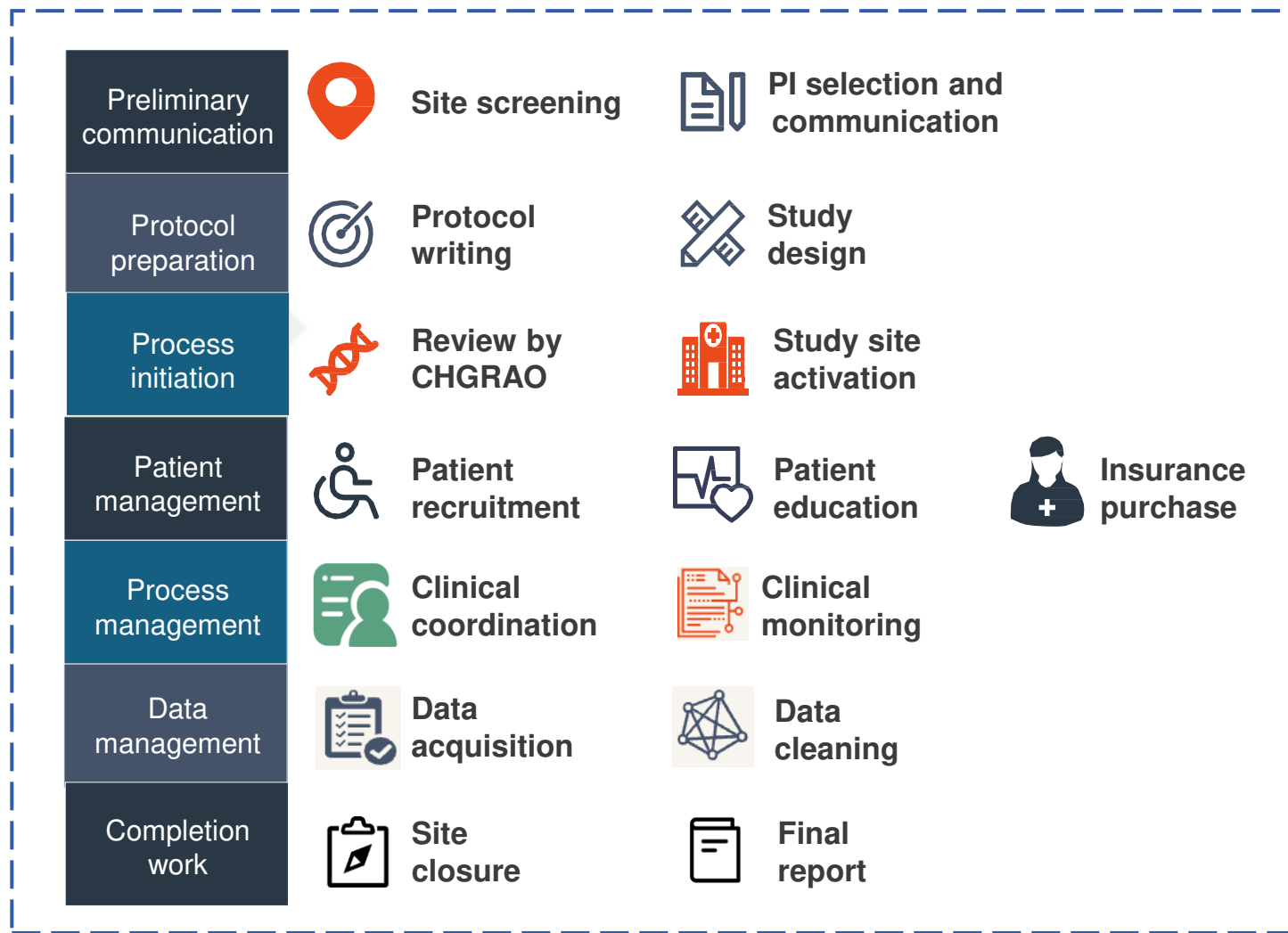
- **Faster** path to clinical proof-of-concept ( $\leq 1/2$  the time of an FDA Ph1 study)
- **Much less expensive** path to clinical proof-of-concept ( $\leq 1/10$  the price of an FDA Ph1 study)
- **Commercially Mature Therapeutic Developers:**
  - Valuable strategy for de-risking/triaging of multiple early-stage clinical program candidates
  - Accelerate strategic “Go/No Go” clinical advancement decisions
- **Start-up Therapeutic Developers:**
  - Valuable strategy for demonstrating clinical impact of select promising candidate(s)
  - Accelerate clinical proof-of-concept and next funding round investment

# uBriGene's Expertise in Chinese IIT Coordination

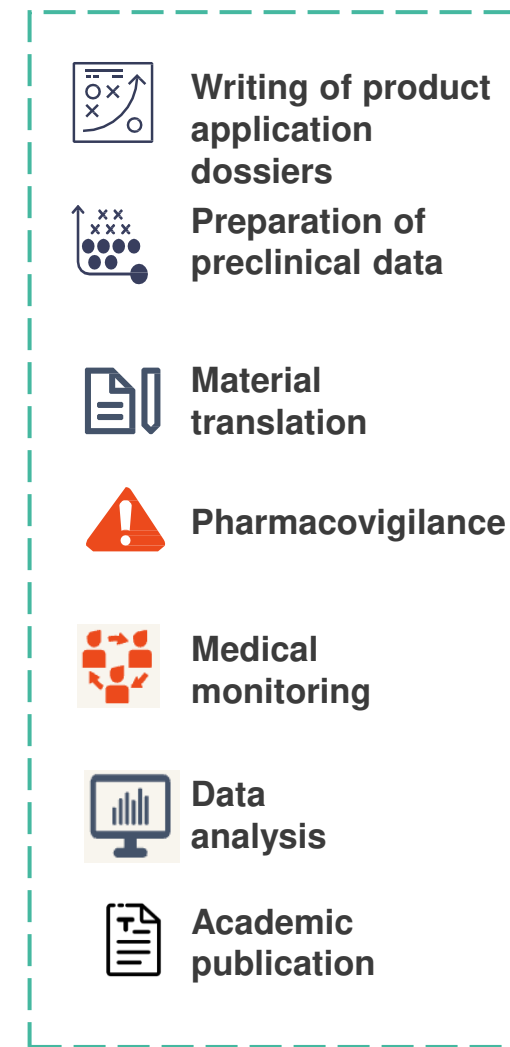


**uBriGene  
Chinese IIT  
Clinical  
Study  
Services**

## Package items



## Optional items



## Proven Team

- Seasoned successful CDMO leadership
- GMP validation in one month

## GMP & QMS Excellence

- 300+ plasmid batches
- 60+ virus batches (AAV, LVV, OV combined)
- 100+ CAR-T/CAR-NK batches
- 100% site audit success rate (at multiple companies)
- iPSC reprogramming, editing and banking platform for allogeneic cell therapy program



## Clinical Success Track Record

- Established 9 FDA DMFs
- Enabled 7 FDA IND submissions
- Support ~10 global IND submissions annually
- Coordination of multiple Chinese IIT studies to accelerate cost-effective clinical proof-of-concept



## Quality Assurance

1

### Personnel Training Program

- Professional knowledge training (CV)
- Training Binders (Regulation): On boarding training, job description, and skill training through on the job training
- Training evaluation

2

### Quality Evaluation

- Standard operating procedures (SOPs) and data records for the approval and release of materials and products
- Quality evaluation for any modification and confirmation of the material supplier management system
- Event handling SOPs (deviation, OOS, Change Control, CAPA)
- Risk Assessment Program

3

### Documentation system

- System design, development, review, approval and release of documentation through the QA Document Control Program SOP

4

### File Management

- Master and executed printed , goods specification, operation procedure and data records in secure location
- Categorized and systematically organized
- Periodically review and revision
- Document retain program

5

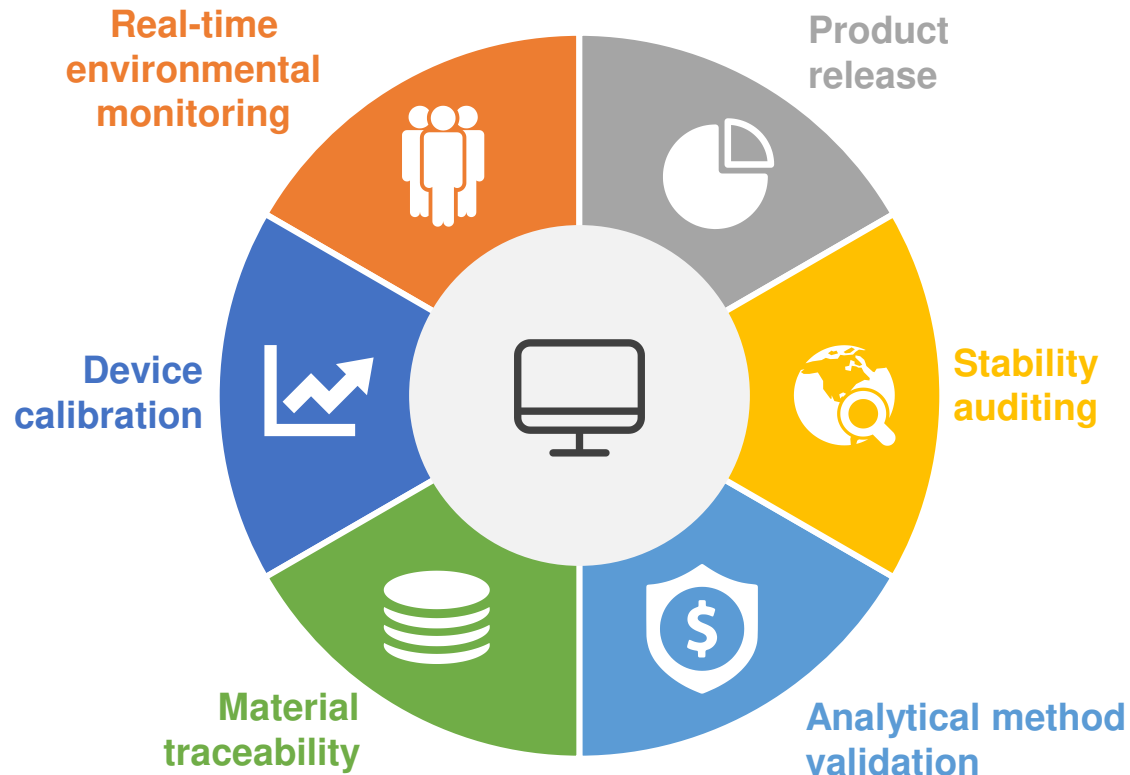
### Manufacturing Management

- Batch production SOP
- Deviation handling SOP
- Environmental monitoring
- Internal inspection
- GMP monitoring service

6

### Regulatory Support

- Dedicated staff to support within the organization (IND, BLA, CMC)
- Complaint Management Program
- Recall Program.



- ✓ Quality inspection platform covers chemistry, microbiology, and biochemistry.
- ✓ Specialized quality control methods are ensured for different products according to the physical and chemical characteristics of different products.
- ✓ The quality system is constantly updated and improved.



# uBriGene Biosciences Inc.

20400 Century Blvd, Suite 125  
Germantown, MD 20874

[www.ubrigene.com](http://www.ubrigene.com)

[contact@ubrigene.com](mailto:contact@ubrigene.com)

Phone: 800 663 2528

