One-stop CDMO-Plus Service Provider for CGT

uBriGene's GMP Facility Highlights

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

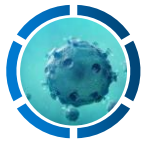
uBriGene's Global Manufacturing Platforms

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

Manufacturing Platform Highlights

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

Manufacturing Platform Highlights

CAR-T, CAR-NK, iPSC

- ✓ **CAR-T: Access to lentivirus production with 100+ CAR-T cases**
- ✓ **iPSC**
  - iPSC cell bank
  - iPSC reprograming 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

The Value of uBriGene-Coordinated Chinese IITs

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 (**≤1/2** the time of an FDA Ph1 study)
- **Much less expensive** path to clinical proof-of-concept (**≤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

Preliminary communication	Site screening	PI selection and communication
Protocol preparation	Protocol writing	Study design
Process initiation	Review by CHGRAO	Study site activation
Patient management	Patient recruitment	Patient education
Process management	Clinical coordination	Clinical monitoring
Data management	Data acquisition	Data cleaning
Completion work	Site closure	Final report

Insurance purchase

Optional items

- Writing of product application dossiers
- Preparation of preclinical data
- Material translation
- Pharmacovigilance
- Medical monitoring
- Data analysis
- Academic publication

Maryland Site : Building upon our ATMP CDMO Excellence

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 System

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

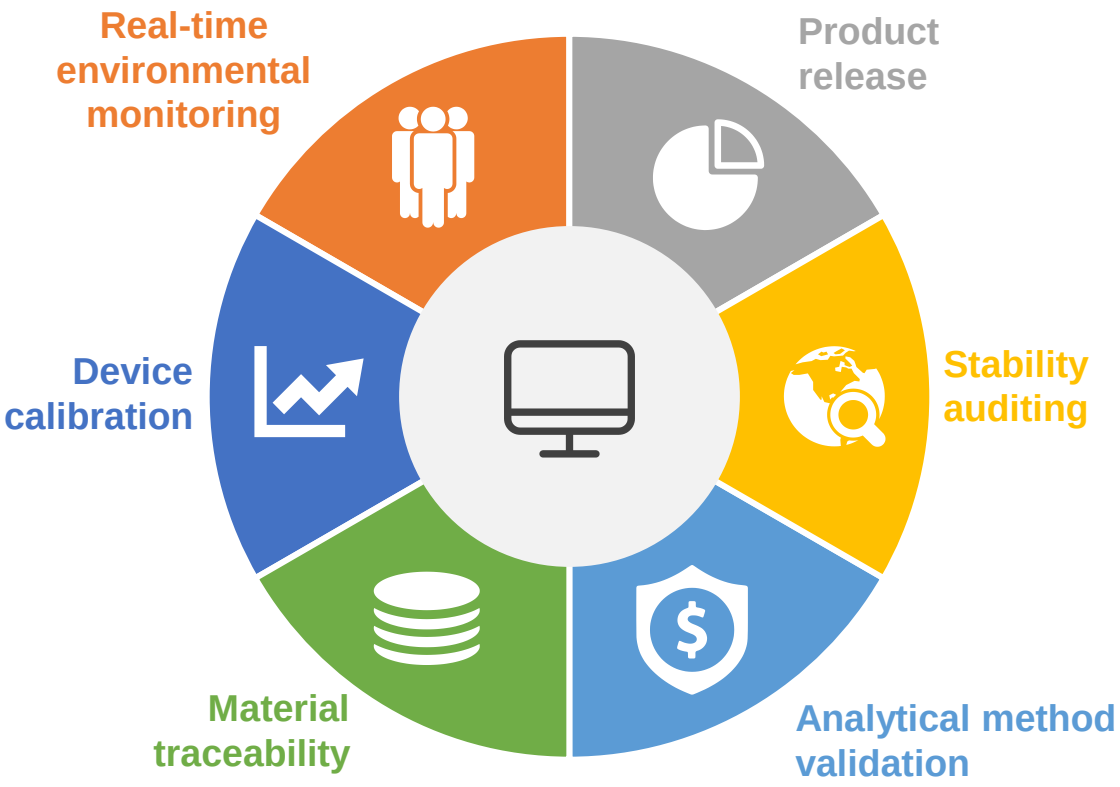
5 Manufacturing Management

- 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 Control



- ✓ 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.

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