CAR-T CELL THERAPY

The development of CAR-T therapy has led to the approval of treatments for leukemia, lymphoma, and multiple myeloma in patients that have failed front-line treatments. The production of these personalized therapies requires a full integrated approach to address complex logistic, manufacturing, analytical and regulatory hurdles.

Critical Raw Materials: GMP ready processes for the receipt/handling of patient starting materials, production of gene of interest and lentivirus helper plasmids, production of lentiviral vectors including access to our lentivirus manufacturing platform using our fully qualified 293T master cell bank and off-the-shelf lentivirus helper plasmids.

Technology Transfer: Extensive experience with transfer of academic and early-stage research grade processes to rapidly establish technology and analytical methods to support process improvements.

Process Development & GMP Readiness: uBriGene has developed a robust closed manufacturing process and testing platform for CAR-T that has produced GMP batches that support IND filing to FDA and CDE. Process development to support process closure and semi-automated manufacturing flows that meet regulatory requirements for transfer to GMP cleanrooms.

Facilities & Clinical Manufacturing: State-of-the-art manufacturing facilities and highly experienced staff to support GMP manufacturing of critical raw materials, drug substances and final drug products.

Analytical Method Development & Qualification: Fully equipped analytical labs to support all method development and qualification in support of in-process, quality control release, and stability program requirements.

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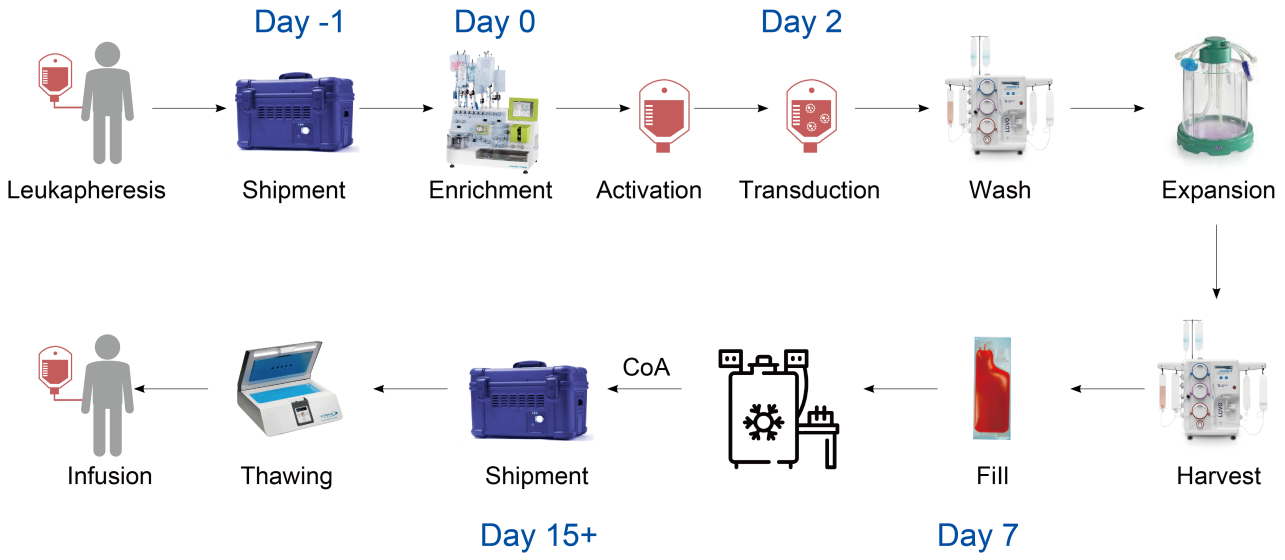
Manufacturing Process Flow

Our Established CAR-T Manufacturing Process Flow: Our manufacturing process is well established with a track record of successful IND approvals and sets the foundation and flexibility to produce a wide variety of gene-modified cell therapies and our client's specific product development needs. We have optimized our plasmid and lentivirus platforms to seamlessly provide high quality vectors to help accelerate CAR-T process development and GMP-readiness for our clients without the need to manage multiple vendors to support product manufacturing.



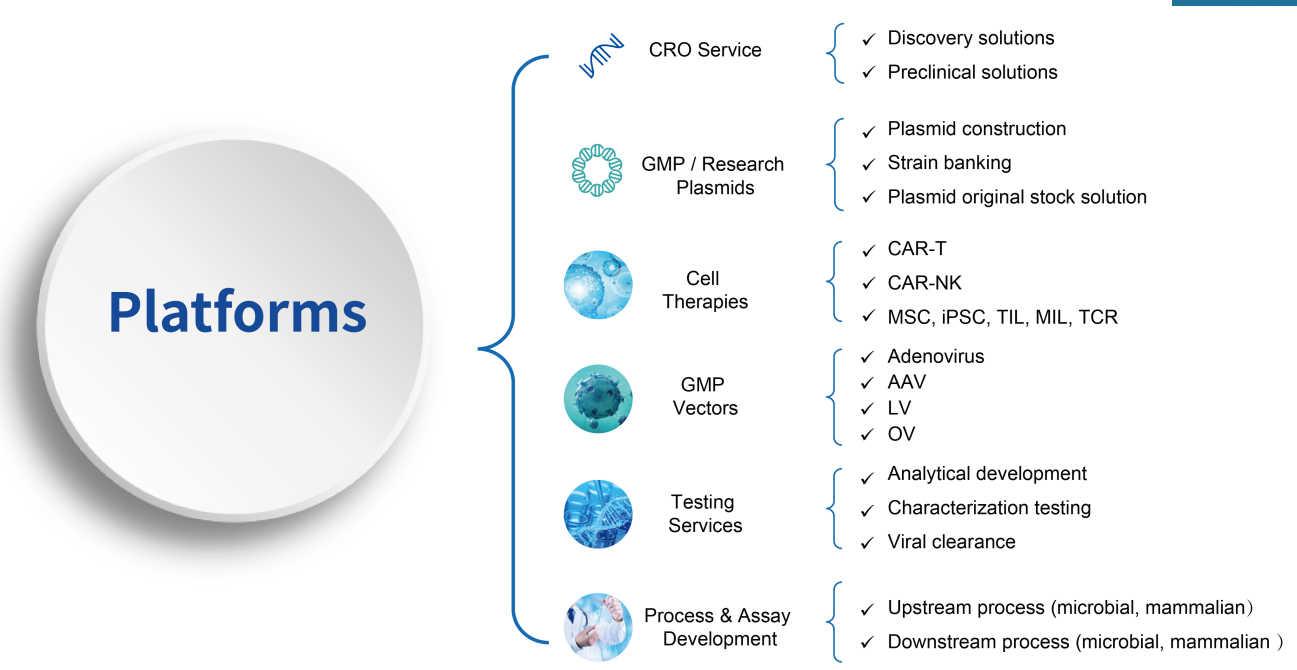
Ensuring Safety and Purity: Each of uBriGene's 16 cell production suites, including 4 in the US amd 12 in China, are equipped with state-of-the-art cell production isolators, providing a dual layer of protection for both the product and operator, while our C+A grade Good Manufacturing Practice (GMP) suites ensure there is absolutely no cross-contamination. A dedicated suite for each patient's batch guarantees the highest standard of personal

Elevating CAR-T with Seamless Manufacturing

We invite researchers, clinicians, and healthcare institutions to join us in our mission to transform cancer treatment.

- Optimized manufacturing process engineered to maintain the integrity and potency of the therapy
- Rigorous manufacturing process control by implementing stringent controls to ensure quality and potency
- Stringent material control in the manufacturing process to address any issues affecting potency
- Reliable potency lot release assays utilizing advanced techniques to test product lots for consistency
- Comprehensive QA and QC capabilities including full-scope testing of final products
- Integrated services from plasmids, viral vectors, to CAR-T manufacturing
- Capabilities of a variety of CAR delivery approaches, plasmids, LVV, RVV, mRNA/ LNP, gene editing
- Successfully delivered 100+ GMP batches

uBriGene Service Platforms



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CAR-T GMP Testing

Assay	Method
pH	Potentiometric method
Osmotic pressure (mOsmol/kg)	Freezing point depression
Appearance	Visual inspection
CAR-T Gene Identification	Gel electrophoreisis
Properties	Visual inspection
BSA residue (ng/ml)	ELISA
E1A gene transfer	PCR
SV40 gene transfer	PCR
Viable cell density (cells/ml)	Cell counter
CAR-T cell typing	Flow cytometry
CAR-T Transduction Efficiency	Flow cytometry
Cell Viability	Cell counter
CAR-T copy number	qPCR
Bacterial endotoxin	Gel-clot method
Mycoplams	qPCR
Sterility	Cultured method
Replication competent Virus	PCR
CAR-T Cell killing efficiency	Flow cytometry

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