

KEY HIGHLIGHTS

CHALLENGES

- 01 Circularization Efficiency:** Generate high-purity circRNA with minimal residues.
- 02 GMP Scalability:** Deliver clinical-grade material in reproducible large batches.
- 03 Quality Assurance:** Establish robust QC to detect and control impurities.
- 04 Therapeutic Readiness:** Enable multivalent RNA delivery for advanced therapies.

CATUG SOLUTIONS

- 01 Efficient Circular RNA Synthesis Technology:** Simplified, scalable in vitro RNA circularization strategies with high efficiency.
- 02 High-Quality Delivery:** One batch successfully produced 2.5g clinical-grade bivalent circRNA-LNP with >90% formulation yield.
- 03 Outstanding Quality Metrics:** circRNA purity up to 99%; LNP encapsulation >95%; LNP purity ~90%; particle size 80–90nm; PDI ≤0.1.
- 04 Advanced QC Platform:** Optimized analytical methods to detect and minimize nicked and linear RNA residues.
- 05 Multivalent Capability:** Demonstrated co-encapsulation of circRNA, mRNA, siRNA, and gRNA, expanding therapeutic applications.

PROJECT SPOTLIGHT

Scaling Up Clinical-Grade circRNA-LNP Manufacturing

How CATUG Delivered a 2.5g Bivalent circRNA-LNP Product with High Yield, Purity, and GMP Compliance.

PROJECT BACKGROUND

Circular RNA (circRNA) is emerging as a powerful modality with superior stability, extended expression, and low immunogenicity, making it highly attractive for vaccines, protein replacement, gene editing, and immunotherapies.

However, circRNA technology still has some key challenges:

- Purity – Efficient circular RNA synthesis with minimal nicked and linear RNA residues.
- Process Scalability – Ensuring reproducibility and robustness at GMP scale.
- Complex Formulations – Enabling co-encapsulation of multiple RNA species.
- Analytical Control – Developing precise QC methods to minimize batch-to-batch variation.

COMPANY OVERVIEW

CATUG is a boutique one-stop CRDMO focused on next-generation therapeutics. Founded in 2021, it is powered by ~200 professionals and operates advanced R&D and GMP facilities in Asia, the United States, and Europe. Guided by four core values—Focus, First, Fast, Flexible—CATUG delivers end-to-end solutions across DNA, RNA, (t)LNP, protein, and Fill & Finish, supporting clients from early R&D to global commercialization. At its core, CATUG combines scientific innovation with scalable, GMP-compliant execution to accelerate high-quality therapies worldwide with speed and regulatory rigor.