bd@catugbio.com | www.catugbio.com

# KEY HIGHLIGHTS

## CHALLENGES

**01 Scale-Up:** Enable consistent large-batch GMP production.

**02 Purity & Stability:** Maintain high mRNA-LNP quality with minimal degradation.

**03 Clinical Readiness:** Deliver sufficient doses for late-stage trials and commercial demand.

## CATUG SOLUTIONS

**01 High Yield:** Achieved >90% formulation yield with ~20g mRNA input.

**02 High Purity:** LNP encapsulation >98%; size 70–80nm; PDI <0.1; mRNA purity loss <5%.

**03 Scalable Output:** One batch supports 4,000 vials (5mg/vial) to 20,000 vials (1mg/vial), covering phase II/III to commercial production.

PROJECT SPOTLIGHT

# Advancing RNA Therapeutics with Scalable, High-Efficiency MaxMix™ Platform

How CATUG Achieved 20g-Scale GMP mRNA-LNP Production, Setting New Standards in Yield, Purity, and Clinical Readiness

## PROJECT BACKGROUND

To support the growing clinical demand for mRNA-based therapeutics, CATUG advanced its proprietary MaxMix™ platform to enable large-scale GMP production of mRNA-LNP. The platform delivers exceptionally high encapsulation efficiency and ensures flexible, reproducible scale-up, making it well-suited for both clinical and commercial needs.

This project demonstrates CATUG's ability to deliver high-quality, clinical-ready drug substances that support next-generation therapies including *in vivo* gene editing, protein replacement, *in vivo* CAR-T, and cancer vaccines.

## 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.