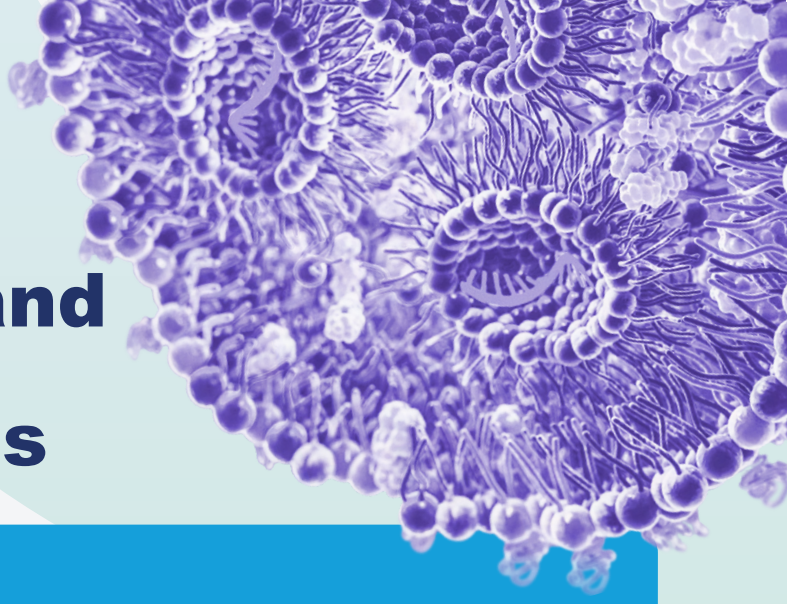
phosphorex

SUCCESS STORY

Process Quality and Control for Novel Gene Editing LNPs



⚠ Problem

A biopharma company developing a novel co-encapsulated gene-editing LNP system was dissatisfied with the batch quality produced by its incumbent supplier. Variability in particle attributes and cargo integrity raised concerns about suitability for preclinical development and clinical translation, prompting the search for a new delivery partner.

Solution

Phosphorex evaluated the co-encapsulated mRNA cargos in the quality LNPs it fabricated following clean process protocols, conducting integrity analysis by capillary electrophoresis to measure a weight ratio of 1.07:1.00 (wt:wt), respectively, for the intact cargo species versus the target theoretical 1:1 ratio (wt:wt)

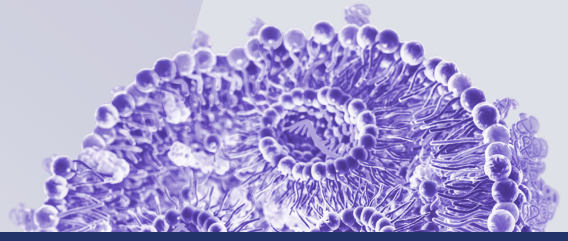
Outcome

Phosphorex delivered a high-quality LNP batch with a 77 nm mean particle size, PDI of 0.039, and 97% encapsulation efficiency following a freeze/thaw cycle at –80°C. mRNA cargo integrity closely matched the theoretical 1:1 ratio. The success led to repeated engagement to advance development.

At Phosphorex, we are committed to helping our partners navigate the complexities of precision drug delivery and advance their programs with confidence. We adapt to your modality, delivery target, and mission, bringing together comprehensive expertise through our Drug Delivery Engine to support every stage of development.

With payload-agnostic, non-viral delivery capabilities, deep experience, and an adaptive approach, we move at the pace of your program; iterating, refining, and aligning as needed. Through close collaboration and clear communication, we serve as a true extension of your team, focused on delivering meaningful progress.

Let's Solve Your Delivery Challenge ›



Particles Engineered for Drug Delivery

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Behind the Solution

A biopharma client came to us after growing frustrated with inconsistent LNP batches from their previous CDMO service supplier. Their goal was straightforward: co-encapsulate two proprietary gene-editing cargos in a well-characterized LNP formulation suitable for preclinical studies. Variability in particle attributes and cargo integrity from prior batches had raised legitimate concerns about whether the material could support preclinical development, let alone clinical translation.

Our team approached the project leveraging phase-appropriate process protocols and rigorous analytical characterization at each stage. Cargo integrity was confirmed by capillary gel electrophoresis, which measured a weight ratio of 1.07:1.00 (wt:wt) for the intact cargo species against the theoretical 1:1 target, a result that gave the client confidence in both the encapsulation process and the analytical methodology supporting it.

The finished batch met demanding quality specifications across the board. Mean particle size was 77 nm with a PDI of 0.039, and encapsulation efficiency reached 97% after a freeze/thaw cycle at –80°C. Endotoxin levels held below 0.3 EU/ml. The high process yield produced enough frozen aliquots to fully support the client's preclinical testing needs without requiring additional manufacturing runs.

The numbers reflected consistent process control from formulation through fill-finish. Co-encapsulating two distinct mRNA cargoes at a defined ratio is technically demanding, and maintaining that ratio while meeting tight particle size and low PDI requirements requires both formulation expertise and disciplined execution. Our team rose to the occasion, which led to the client's decision to return for a follow-on optimization project. For gene-editing programs where cargo stoichiometry matters, innovators need this kind of process reliability to advance early feasibility work to material that can be effective in later phases of development.

Sarah Francis

Analytical Scientist

With a Bachelor of Science, Biomedical Engineering from Worcester Polytechnic Institute and a passion for particulate-based drug delivery, Sarah is rapidly climbing the ranks within Phosphorex's analytical team.

> Not many CDMOs have the expertise to co-encapsulate two distinct mRNA cargoes at a defined ratio and maintain that ratio while meeting tight particle size and low PDI requirements. I am proud to work alongside my colleagues, allowing Phosphorex to bring this much-needed expertise to the table.