Millipore®
CTDMO Services

Early Formulation Screening Service

Bringing your Nucleic Acid modalities into the optimal Lipid Nanoparticle formulation

As part of our globally integrated mRNA-LNP CDMO capabilities, the Early Formulation Screening Service, located at our headquarters in Darmstadt, Germany, encompasses a best-in-class expert team that is dedicated to screening and optimizing lipid nanoparticle (LNP) formulations for your nucleic acid payloads.

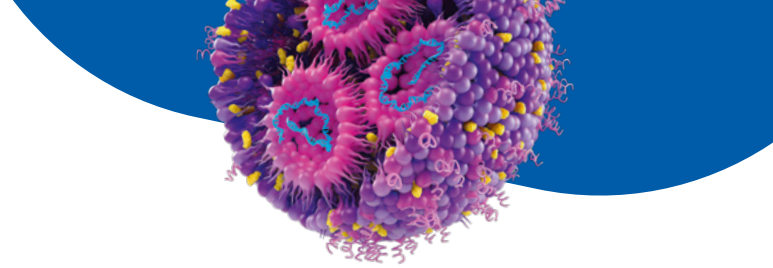
We overcome your challenges in LNP formulation development

Lipid nanoparticles are essential to ensure safe and efficient delivery of nucleic acids to cells.

These particles, typically composed of four different lipids, provide a protective bubble for the delicate RNA molecules. Effortless? Most certainly not. The lipid type, the identification of the appropriate composition that provides effective results, the optimal manufacturing process of LNPs, the development of advanced characterization techniques, or long-term stabilization, are only a few examples of technical challenges that we, as experts in the field, tackle for you.

Our key technical strengths

- Expertise across multiple nucleic acid modalities and lipid-based drug delivery systems
- Access to state-of-the-art ionizable lipids from multiple libraries
- Advanced analytical characterization including *in vitro* cell culture studies
- Dedicated stability studies at desired storage conditions
- Broad variety of mixing technologies
- A full CDMO service from mRNA/lipid manufacturing to GMP formulation manufacturing including Fill and Finish



Get the optimal formulation for your nucleic acid and bring it to the next level

The Early Formulation Screening service is dedicated to the preclinical space, within our globally connected mRNA-LNP CDMO offering. Whether you have experience in LNP formulation or not, we customize our offer and adapt it to your needs. Make use of our high-quality raw materials and Early Formulation Screening service to advance your project to first-in-human/clinical studies.

Preclinical

The Early Formulation Screening service applies three development steps to your project.

1 Formulation Screening

Ionizable lipids are considered as key excipients driving the success of LNP delivery systems.

Our state-of-the-art portfolio has a proven track record of success in different applications. We identify the most promising lead lipids for your nucleic acid payloads and offer thorough analytical characterization including *in vitro* testing.

2 Formulation Optimization

We refine the formulation composition and perfect the lead mixture for maximal/optimal efficacy.

We provide advanced analytical characterization, including extended *in vitro* studies to allow prediction of biological behavior.

3 Preclinical Scale-Up

To support GLP toxicology and stability studies, we focus on finding the best manufacturing conditions for your formulation and transition bench-scale unit operations to their scalable counterparts.

We provide you with results from long-term stability studies. When the optimized formulation is ready to advance towards the clinical phase, our experts ensure the technology transfer to our in-house GMP manufacturing site.

Discover more about our LNP CDMO offering:

www.sigmaaldrich.com/services/contract-manufacturing/mrna-and-lnp-formulation-ctdmo-services

Find out more about our integrated mRNA-LNP offering on our website: **sigmaaldrich.com/mrna**

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