Millipore®
CTDMO Services

MERCK

Early-Stage Development of LNP Formulations

Developing and bringing your formulation to the clinical phase.

Our Indianapolis, Indiana site (formerly Exelead) specializes in parenteral, lipid-based drug delivery solutions, with a strong preclinical development process and a proven track record in lipid nanoparticle formulation.

We have strategically placed ourselves as a specialized pharmaceutical company, providing end-to-end service for clients that operate in this market. Because we maintain integrity to this focus, we continue to operate as industry experts.

Our offering

Proven track record with decades of experience of working specifically with lipid-based solutions.

Advanced analytical testing equipment and expertise.

A smooth transition from preclinical development to process scale up, GMP manufacturing of clinical and commercial batches.

Preclinical development includes

- Raw Materials Selection
- Formulation Development
- Analytical Method Development
- Microbial Method Suitability, Feasibility & Robustness
- Manufacturing Process Development and Optimization
- Pilot Batches

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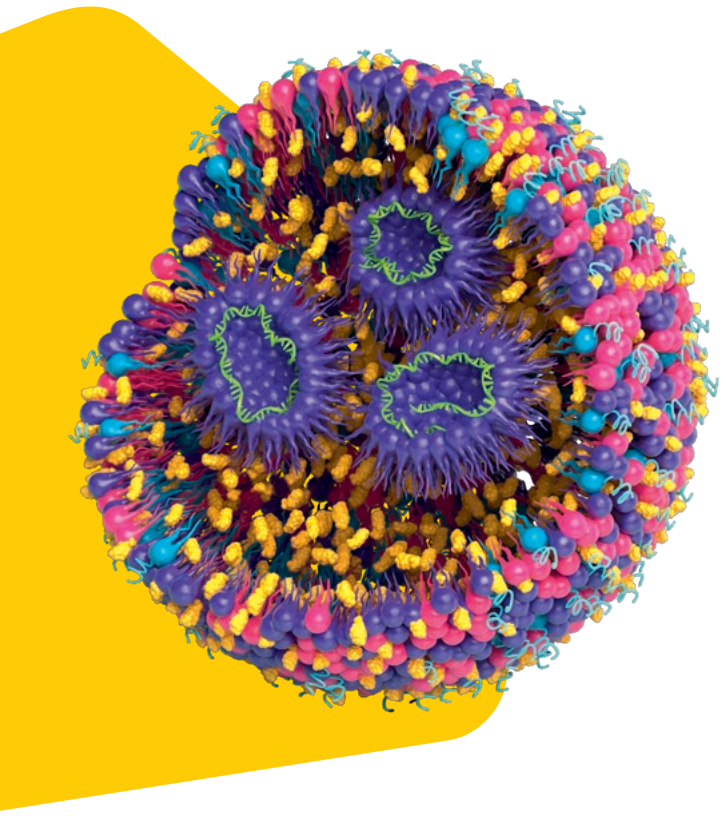
Establish precise analytical test methods to ensure the integrity of your product.

We can develop new methods or work with your existing methods to determine feasibility and optimize your test procedures. When phase-appropriate, method validation procedures are applied to confirm the adequacy of each test method.

- Analytical Method Development
- Method Qualifications/Validations/Transfers
- Stability testing according to ICH guideline
- API and Raw Material Testing
- On-site Microbiology Testing
- Expertise in lipid nanoparticle, liposome, and PEGylated formulations



Perfect your formulation and define the steps required to manufacture it.

We work with our clients to take their molecule of interest and formulate it into a drug product worthy of clinical trials and commercial development.

- **Design of optimal formulation for the API**
  Selection of excipients and vendors, synthesis of bench-scale samples for client-based screening assays and *in vivo* protocols
- **Establishment of optimized process to generate nanoparticles**
  Variables include mixing flow rates, ratios, concentrations and temperatures
- **Incorporation of extrusion or homogenization operations to size nanoparticles**
  If required
- **Development of tangential flow filtration process**
  Optimization of shear rate, transmembrane pressure and membrane selection
- **Design of filtration/clarification operations**
  Filter selection studies, flux/throughput optimization
- **Scale-up of all processes**
  Lipid nanoparticle generation to fill-finish
- **Transfer of formulation to cGMP environment**
  In-process hold studies, temperature studies, nitrogen blanket studies, material compatibility

Beyond preclinical development solutions, we offer clinical and commercial contract manufacturing as well as filling services. Contact us for more information!

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