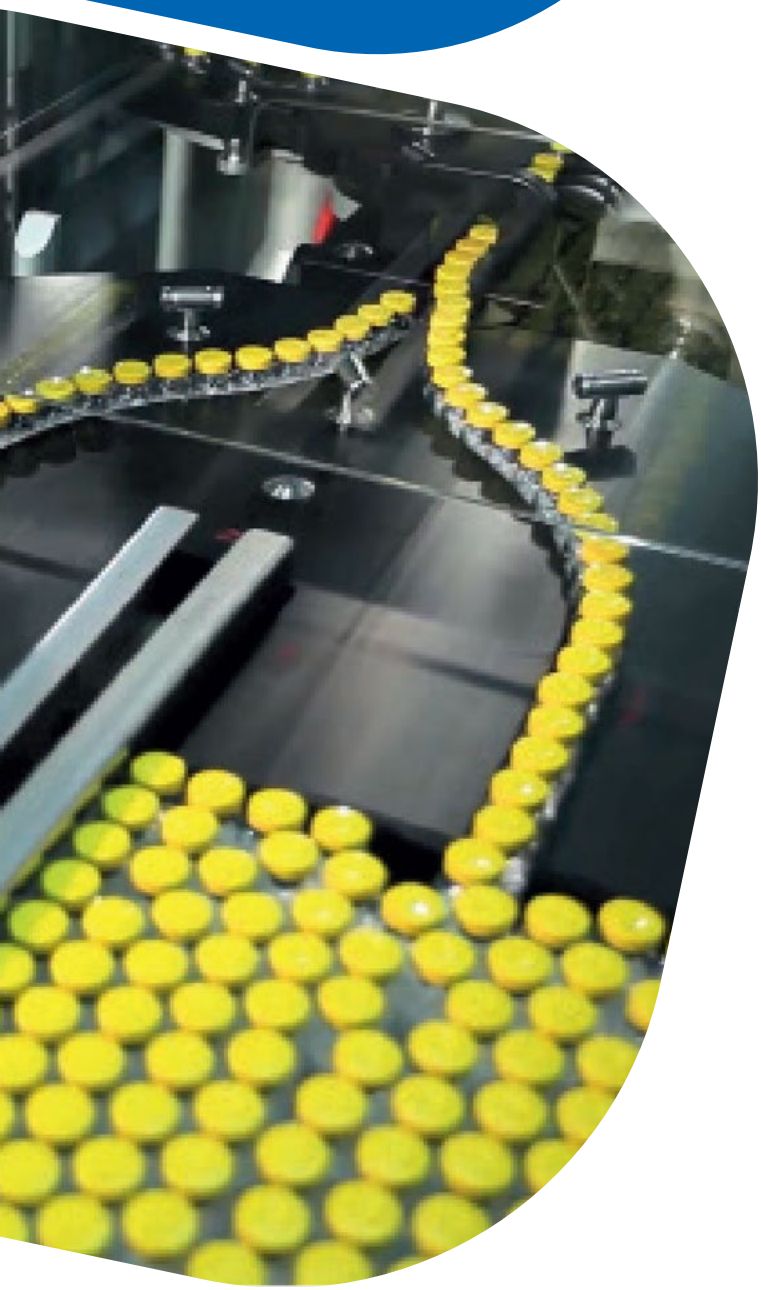
Millipore®
CTDMO Services

MERCK



GMP Manufacturing of LNP formulations

From clinical supply to commercial manufacturing

Our Indianapolis, Indiana site (formerly Exelead) has a worldwide reputation for handling commercial contract manufacturing and filling for small to large pharma clients. We also help clients with manufacturing and fulfillment during the clinical trial process.

We manufacture a wide range of sterile products, with a specialization in complex biological products, specifically lipid nanoparticle, liposomal, and PEGylated formulations. We can customize a pharmaceutical manufacturing process to your exact specifications, offering aseptic product manufacturing in a closed system as well as end-point sterile filtration.

Experience

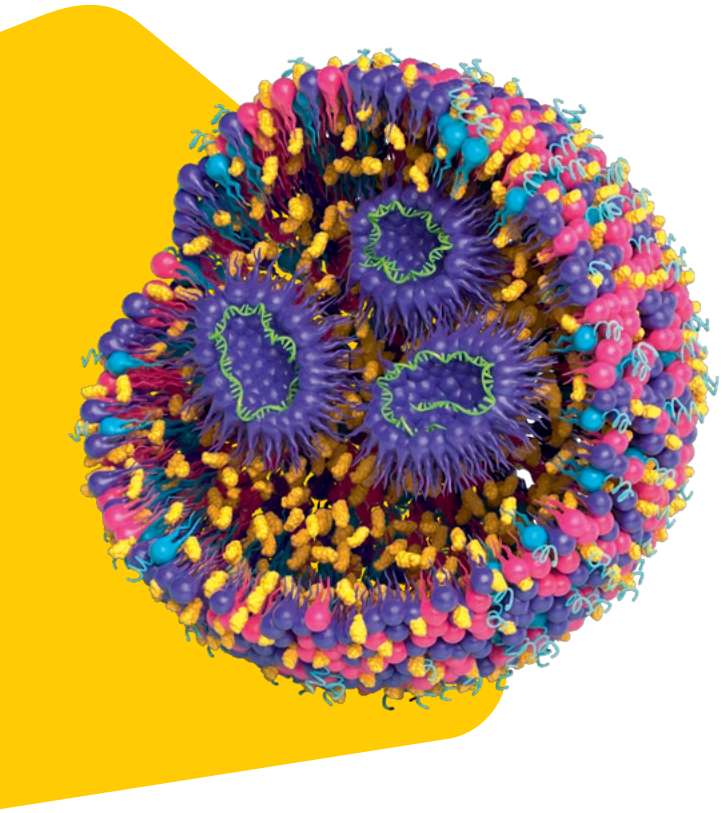
- Lipid Nanoparticles (LNPs)
- Liposomal Complexes
- PEGylated Molecules
- Suspensions
- Small Molecules
- Nucleotides (mRNA, siRNA, RNAi, saRNA, DNA, Duplexes)
- Proteins
- Aseptic Preparations Proteins

GMP Manufacturing of LNP formulations

Our Facilities

Our manufacturing operations utilize clean rooms qualified to GMP and ISO standards. To ensure quality, consistency, and compliance, we employ:

- Aseptic Processing and Filling areas that meet ISO 5 (Grade A) standards for environmental control
- Barrier and isolator technologies to ensure product sterility during filling and capping operations
- Formulation areas that meet ISO 8 (Grade C) standards for environmental control
- Manufacturing support areas that meet ISO 8 (Grade C) standards for environmental control
- Proceduralized, standardized methodologies for HEPA recertification



- Process and product-specific bioburden monitoring plans to ensure manufacturing process control
- Daily and annual annual environmental baseline monitoring to detect changes in the site microbial profile and confirm continuing effectiveness of sanitizing agents and procedures

Manufacturing Line Capabilities

We support fill/finish for both glass and plastic vials. Our flexible manufacturing accommodates:

Closed RABS System

Batches under 100 vials to batches of 100,000 vials

Batch volumes of <1 L to 1,200 L

Isolator System

Integrated lyo

Batch volumes <1 L to (approx.) ~500 L

Ready to use ISO format vials

Supporting Services

To enable manufacturing activities, we offer full support services including packaging and inspection, quality control, supply chain and distribution. We recognize that navigating pharmaceutical manufacturing, clinical trials, logistical complexities and strict regulations requires a deep level of experience and expertise. We are here to guide you at every step with global regulatory expertise and service.

Visit:

SigmaAldrich.com/MilliporeCTDMOServices

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

MK_FL9181EN Ver. 1.0 46831 03/2023