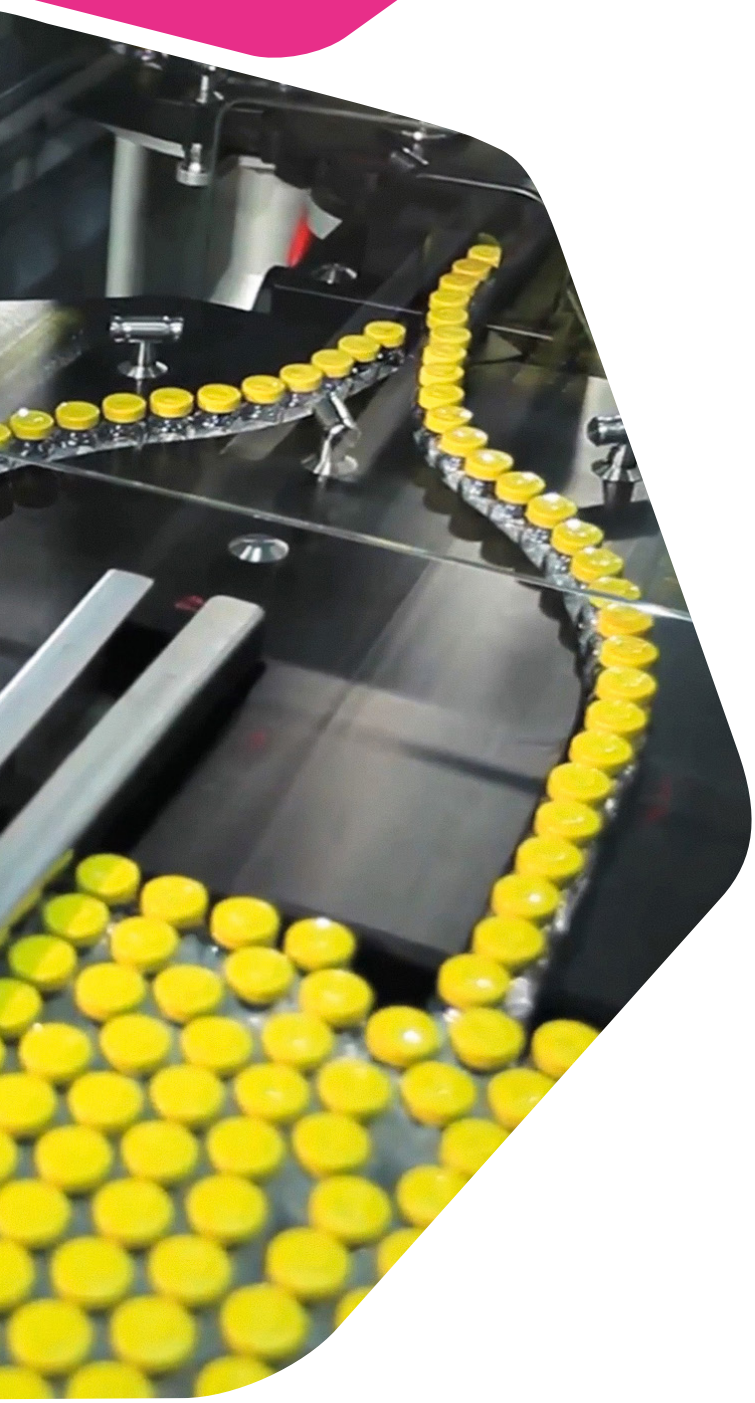
SAFC®

Pharma & Biopharma Raw Material Solutions

MERCK



GMP Manufacturing Capabilities

Commercial Contract Manufacturing | Clinical Supply

Our newly acquired site of Exelead® CDMO Services 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.

See an overview of our tech transfer process at **exeleadbiopharma.com** ›

Experience

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

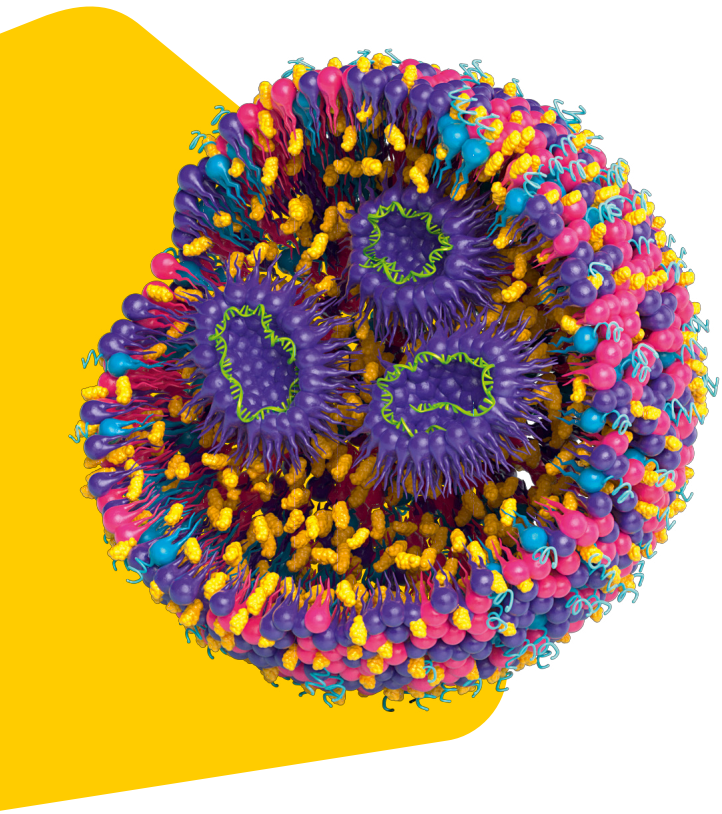
Commercial Contract Manufacturing | Clinical Supply

GMP Manufacturing Capabilities

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 have 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 there to guide you at every step. With world-wide reach, we supply to these markets for extensive regulatory history: United States, Japan, Europe, North America, South America, and the Middle East.

Exelead is now part of Merck.

To place an order or receive technical assistance in Europe, please call Customer Service:
France: 0825 045 645
Germany: 069 86798021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840
Or visit: **MerckMillipore.com/offices**
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