SAFC®

Pharma & Biopharma Raw Material Solutions

MERCK

Early-Stage Development

Preclinical Development

At our newly acquired site of Exelead® CDMO Services we specialize 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 niche 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

Decades of experience working specifically with lipid-based solutions.

Advanced analytical testing equipment and expertise.

A smooth transition from preclinical development to process scale up, clinical batch and cGMP manufacturing.

Preclinical development includes

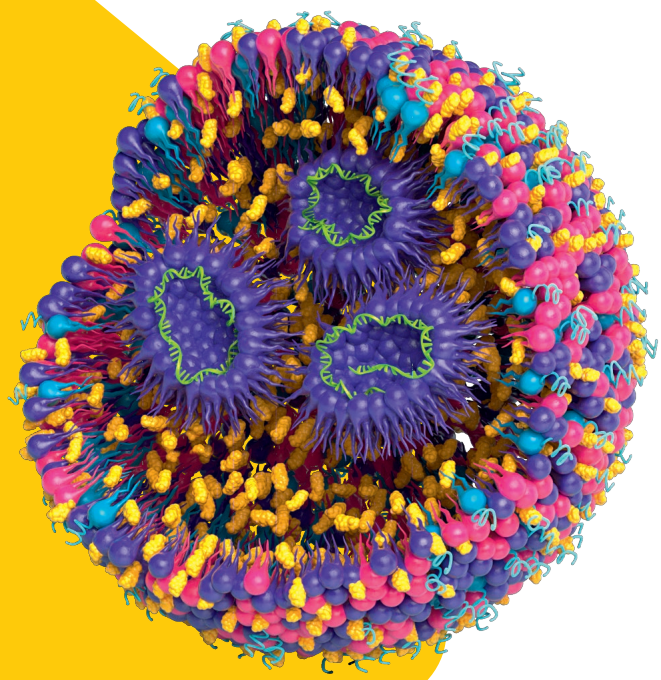
- Raw Materials Selection
- Formulation Development
- Analytical Method Development
- Microbial Method Suitability, Feasibility & Robustness
- Manufacturing Process Development and Optimization
- Pilot Batches

Commercial Contract Manufacturing | Clinical Supply
Early-Stage Development

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

In addition to our preclinical development solutions, we provide clinical and commercial contract manufacturing as well as filling services.

Learn more about analytical method development and validation at **exeleadbiopharma.com** ›

Exelead is now part of Merck.

To place an order or receive technical assistance in Europe, please call Customer Service:
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