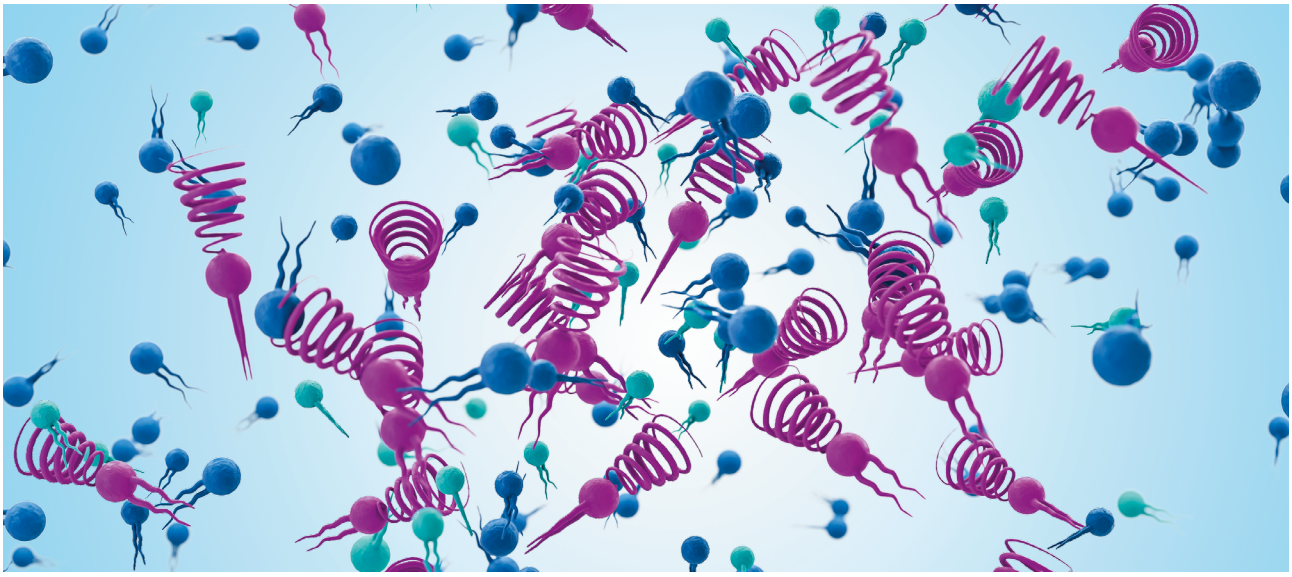
Your partner for high-quality GMP lipids

More than 30 years' experience with lipid nanoparticles (LNPs) and other nanomedicines



Genetic technologies are rapidly evolving and have great potential to treat a range of acquired and hereditary diseases, from cancer and metabolic disorders to infectious diseases. Lipid nanoparticles (LNPs) are the preferred delivery system in gene therapy because they enable the transport and delivery of a variety of molecules to cells – including RNA. Consistent supply of high quality lipids is critical to the development and commercialization of new vaccines and therapies. Working with Evonik as your integrated partner helps you save time and ensure the success of your project.

Evonik has over three decades of experience formulating liposomes and lipid nanoparticles (LNPs) using variety of different lipids. Evonik also manufactures lipids, including those used in mRNA COVID-19 vaccines. For example, PhytoChol® is our non-animal-derived cholesterol used for mRNA delivery from LNPs and cell culture applications. We work together with leading players in this field to supply custom lipids that help realize the potential of gene therapies and their future applications.

In this new era of medicine, specialized contract development and manufacturing partners with a high degree of flexibility will play a crucial role in the success of these therapies. Evonik, as a fully integrated solutions provider for advanced drug delivery, can support you at any stage of the development process including lipid development and manufacturing, formulation development, clinical supply production and commercial manufacturing.

EVONIK
Leading Beyond Chemistry

SUPERIOR DEVELOPMENT AND MANUFACTURING CAPABILITIES FOR LIPIDS

We harbor a deep understanding of liposomes and LNPs, including formulation, scale up, and characterization, and as a result we recognize the crucial role of lipids in these formulations. We support our clients with custom lipid projects by combining this understanding with decades of expertise in process development, analytics, scale up, validation and GMP manufacturing. Regardless of your current scale and requirements, Evonik can support with non-GMP and GMP capabilities from small-scale through large-scale production.

As an integrated solution provider, we combine all of these capabilities in one package.

Chemical process R&D: route scouting, specific catalyst screening and development, process development, process transfer.

Flow chemistry: development of continuous processes for intermediates and final products for pilot and large-scale production.

PEGs and mPEGs: development and manufacturing of PEGs/mPEGs for corresponding backwards integration into key raw materials for PEGylated lipids.

Purification technology: purification processes by chromatography, and thermal separation processes such as distillation and crystallization, from lab to multi-ton scale.

Particle engineering: crystallization, milling, spray drying to control polymorphism, particle size, purity and other properties.

Analytical Services: a wide range of analytical capabilities required for lipid characterization, expertise in development or transfer of methods, including method validation.

A BROAD, FLEXIBLE RANGE OF SERVICES FOR YOUR LIPID DEMAND

Seamless support for your project from feasibility to launch including:

- Launch-focused process development for commercial supply
- Analytical method development services
- Identification and characterization of impurity profiles
- Extensive process validation and stability studies
- non-GMP samples for compatibility studies
- cGMP compliant manufacturing at any scale
- Established quality systems
- Global regulatory support including DMF preparation and filing

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