TRANSFERRA Nanosciences Inc.

Leaders in Lipid Nanoparticle Drug Delivery Systems

TRANSFERRA Nanosciences Inc. (formerly Northern Lipids Inc., NLI) is a Contract Development and Manufacturing Organization (CDMO) that provides Chemistry Manufacturing and Controls services and products to pharmaceutical and biotechnology companies engaged in drug development. The company specializes in both the development and manufacture of complex drug delivery systems using lipid nanoparticle science. TRANSFERRA combines formulation, analytical, and GMP manufacturing services with established expertise in lipid nanoparticle technology to bring first in class formulations from bench to bedside for its clients.

GMP Manufacturing Services

The TRANSFERRA cleanroom facility includes ISO 7 compounding areas and an ISO 5 filling suite in an ISO 6 background. The cleanroom space and supporting utilities were designed specifically for the manufacture of nanoparticles and more specifically, liposomes. Custom-designed isolators employed in the cleanroom provide protection for operators and manufacturing areas from highly potent Active Pharmaceutical Ingredients. The manufacture of clinical trial material complies with U.S. and European regulations. TRANSFERRA provides full service GMP manufacturing including acquisition of raw materials, identity testing, drafting the master batch record, compounding, filling, inspection, labeling, release testing, and shipping to clinical distribution sites. Analytical support for GMP manufacturing includes in-process testing, release testing, and stability studies.

Process Development and Scale-Up Services

TRANSFERRA specializes in manufacturing process design and implementation of drug-carrier nanoparticle complexes and lipid nanoparticle formulations at small, intermediate, and large/commercial scales. This enables manufacturing of formulations for GLP toxicology studies and clinical testing in TRANSFERRA's state-of-the-art manufacturing facilities and transfer of drug product manufacturing to commercial facilities.

Core manufacturing technologies include extrusion, tangential flow filtration (TFF) and sterile filtration with availability of medium to large scale equipment. TRANSFERRA also has experience in extrusion-free nanoparticle formation based on controlled mixing technologies. The company uses isolator technology for the manufacture of high potency/cytotoxic drugs and employs aseptic processing using single-use bioprocess technologies.

Analytical Services

As per FDA's draft guidance on liposomal drug production, product performance is assessed using a diverse set of physical-chemical measurements such as particle size distribution, in-vitro release analysis, encapsulation versus free drug quantitation, and drug to carrier ratio determination. These measurements allow the development and optimization of new formulations with specific pharmaceutical performance characteristics.

TRANSFERRA offers analytical tech transfer, assay development, method qualification/validation and routinely provides cGMP release and ICH stability testing on products consisting of conventional small molecules, peptides, proteins, lipids, carbohydrates, and nucleic acids. TRANSFERRA provides the chemistry expertise and equipment for the analysis of these types of new drug formulations.

Formulation Development Services

TRANSFERRA focuses on the development of lipid nanoparticle-based drug formulations such as liposomes, micelles and emulsions, and also has experience with polymer-based formulations and conventional surfactant and cyclodextrin-based formulations. The company works with virtually all drug classes including small molecules, peptides, proteins, mRNA, siRNA and DNA oligonucleotides.

TRANSFERRA formulation development capabilities include pre-formulation studies to characterize the physical and chemical properties of the Active Pharmaceutical Ingredient and assess compatibility with excipients. The company develops and screens formulation prototypes to identify candidates with relevant pharmaceutical properties (size, chemical & physical stability, controlled release) and then identifies a suitable manufacturing process. TRANSFERRA manufactures promising formulation candidates for PK, efficacy and toxicity testing in animals to identify a lead candidate and scale up the lead to enable GLP toxicology studies.

Examples of formulation development programs at TRANSFERRA include synthetic vaccines, lipid nanoparticle (LNP) formulations of RNA-based and DNA-based drugs, formulations of hydrophobic, difficult to solubilize drugs, controlled release formulations and ligand-targeted nanoparticle formulations.

Products

TRANSFERRA manufactures custom-built LIPEX® extruders for large scale manufacture of commercial drug products in addition to benchtop LIPEX® extruders for drug research and process development applications.

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