

# From Research & Discovery

# Through Clinical Trials

# To Commercialization

Technology Transfer

Formulation Screening and Optimization

R&D Material Production

Process Development and Scale-up

Production of Clinical Materials

Further Process Scale-up and Optimizations

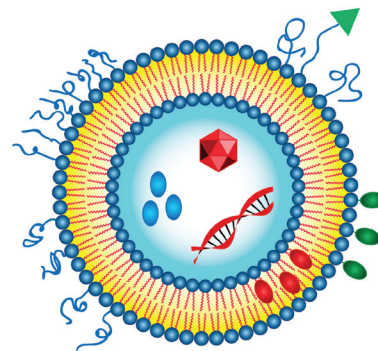
Manufacturing of Commercial-scale Bulk Product

## At the R&D Stage

The process starts at the R&D stage. Our Formulations Team has considerable experience working with Avanti lipids to produce lipid formulations with the exact properties you need for a successful project. Whether you have developed your own formulation and need help scaling up the process, or you want Avanti to design a lipid-based drug delivery system to achieve your product goals, we have the capability to design and deliver any formulation imaginable. And if the perfect lipid for your formulation does not currently reside in our extensive catalog, chances are our outstanding lipid synthesis team can prepare it.

### R & D Process:

- Offer formulation expertise and assist in the design of lipid-based formulations
- Provide the full Avanti lipid catalog for custom formulations as small as 25 mg
- Provide custom synthesis of lipids for your formulation
- Make custom lipid formulations to meet your specifications or prepare custom lipid blends
- Provide lipid-based drug delivery systems that encapsulate, conjugate, or complex APIs, nucleic acids, proteins, and small molecules.
- Produce 1 mL – 50 L lipid formulations using:
  - Extrusion
  - High-pressure Homogenization
  - Sonication
  - High-shear Homogenization
  - Microfluidics



- Polyethylene glycol
- Ligand
- DNA/RNA/siRNA
- Phospholipid
- Hydrophilic drug
- Crystalline drug
- Hydrophobic drug
- Surface-conjugated drug

## At the Clinical Stage

The clinical process starts with the assignment of a dedicated Project Manager, ensuring that your project is completed within your expected timeline. Your Project Manager works in partnership with you through the following process.

### Clinical Process:

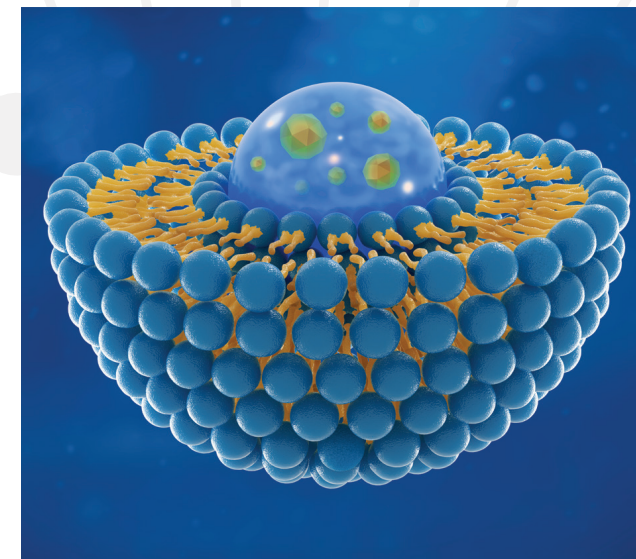
- Transfer our small-scale manufacturing to larger-scale (1 L – 55 L batches)
- Manufacture materials for clinical trials in our animal product-free, cGMP manufacturing area
- Manufacture adjuvant-containing liposomes or nanoparticles in our cGMP adjuvant manufacturing suite
- Assist in the identification and selection of a sterile-filtration facility for parenteral products
- Coordinate inter-departmental efforts including analytical method development, qualification and validation, stability, and regulatory support

## At the Commercial Stage

Our Formulations Division offers complete product cycle services that support oral formulations for commercial production. For parenteral products, we have established relationships with sterile lipid formulation product manufacturers for a seamless transfer of your product to aseptic commercial production.

### Commercialization Process:

- Scale up manufacturing to support your product needs
- Promise to give your product the same care that is given to our lipids, still the best in the industry after 50 years
- Seamless transition to commercial drug product manufacturing



# Formulations ▼

The Avanti Formulations Team can help develop a suitable formulation for your lipid-based formulation. With the vast library of Avanti lipids and state-of-the-art equipment at our disposal, this experienced team can produce surface-labeled, PEGylated, fluorescent, and other lipid formulations, while working closely with our Lipid Analysts to ensure Avanti quality.

Let us help you do amazing things with our lipids!



- **Discovery**
- **Proof of concept**
- **Small scale manufacturing**
- **Process scale-up**
- **Clinical trials**
- **Commercial realization**

The Avanti Formulations Division can help you at each step.

To find out more about how we may assist you with your liposome or nanoparticle needs, please contact us at:

✉ [liposomes@avantilipids.com](mailto:liposomes@avantilipids.com)

☎ (205) 663-2494

**We look forward to working with you!**



## Research Products

Highest Purity Lipid Reagents

## cGMP Manufacturing

API & Contract Manufacturing

## Adjuvants

Vaccine Development

## Analytical Services

Lipid Analysis

## Lipidomics

MS Standards, Antibodies & Lipid Toolbox

## Formulations

Liposomes & Nanoparticles

## Equipment

Liposome Production Tools

## Custom Services

Synthesis & Beyond

## How may we help?

- Toll-Free USA/Canada (800) 227-0651
- Toll-Free USA/Canada (800) 229-1004
- Direct-Dial USA/International (205) 663-2494
- Direct-Dial Fax USA/International (205) 663-0756
- Orders: [orders@avantilipids.com](mailto:orders@avantilipids.com)
- Inquiries: [info@avantilipids.com](mailto:info@avantilipids.com)
- Technical questions: [technical@avantilipids.com](mailto:technical@avantilipids.com)



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## Formulations Division

### Liposomes and Nanoparticles



## More than Lipids

Solutions for the entire product cycle:  
research to commercialization.