From Research & Discovery ▶ Through Clinical Trials ▶ To Commercialization

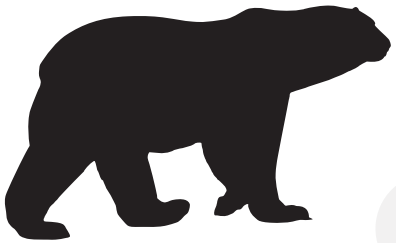
Technology Transfer | Process Development | R&D Material Production | Dedicated Project Manager | Process Scale-up | Manufacturing of Phase I through III Materials | Further Process Scale-up | Manufacturing of Commercial-scale Pharmaceuticals

At the R&D Stage

Avanti will establish a Development Team to ensure the smooth development of your API. Our experienced Organic Chemists will oversee the process development and scale-up while our Lipid Analysts guarantee that Avanti quality prevails at each step.

R&D Process:

- Synthetic process development
- Synthetic scale-up development (non-cGMP and cGMP)
- Analytical method development and validation
- Full scale cGMP manufacturing with process validation



At the Clinical Stage

Your assigned Development Team will partner with you in creating a strategy tailored to each compound.

Clinical Process:

- Master Plan for Development
  Short and long term strategy
- Process development
  Synthetic and analytical methods
- Pre-clinical Trials and Tox Studies
  Initiate cGMP manufacturing
- IND filing
  Specification development, product characterization, analytical method development/validation.
- Scale-up manufacturing (cGMP) and ICH stability
- Clinical Trials (Phase I & II)
  Manufacturing and regulatory support

At the Commercial Stage

The Development Team will work with you to achieve your economic goals and to satisfy regulatory requirements.

Commercial Process:

- Clinical Trials (Phase III)
  Establish final scale for product launch
- Commercial Scale-up and Process Validation
  Finalize manufacturing process for product launch
- NDA Filing
  CMC data and Drug Master File support
- Product Launch
- Niche Commercial Manufacturing

Stock GMP/API Lipids

Please contact our Development Team or check the website for our selection of in stock GMP/API lipids.

- Process development
- Small-scale manufacturing
- Process scale-up
- cGMP manufacturing for tox studies & clinical trials
- IND to NDA regulatory support
- Commercial realization

Our cGMP Manufacturing Division can help you at each step.

To find out more about how we may assist you with your clinical product development needs, please contact us at:

gmp@avantilipids.com
(205) 663-2494

We look forward to working with you!

Avanti® Polar Lipids, Inc.

Research Products
Highest Purity Lipid Reagents

cGMP Manufacturing
API & Contract Manufacturing

Adjuvants
Immunotherapy & Vaccine Development

Analytical Services
Lipid Analysis

Lipidomics
Mass Spec 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
- Inquiries: info@avantilipids.com
- Technical questions: technical@avantilipids.com

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Avanti® Polar Lipids, Inc.

cGMP Manufacturing Division
API & Contract Manufacturing

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More than Lipids
Solutions for the entire product cycle: research to commercialization.