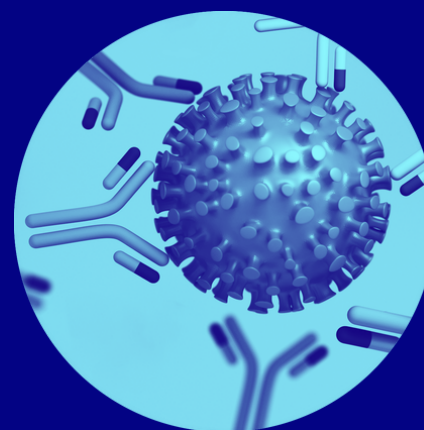
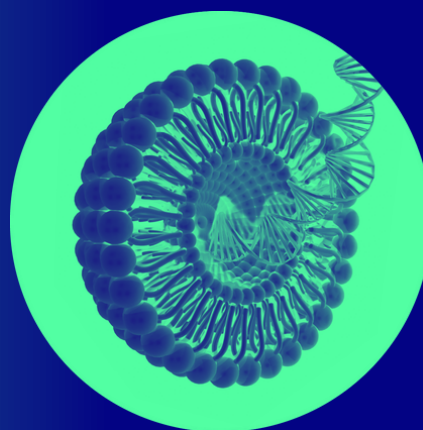
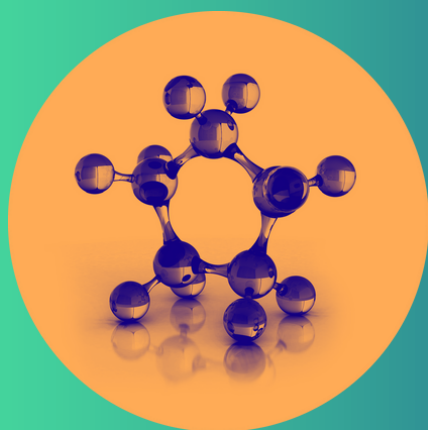


cGMP Manufacturing Division

Contract Manufacturing



For over 40 years, Avanti has been the trusted partner in excipient and API technology development, offering comprehensive services from process chemistry to regulatory support, ensuring quality from pre-clinical stages to commercial launch.

Smart science to improve lives™



CRODA

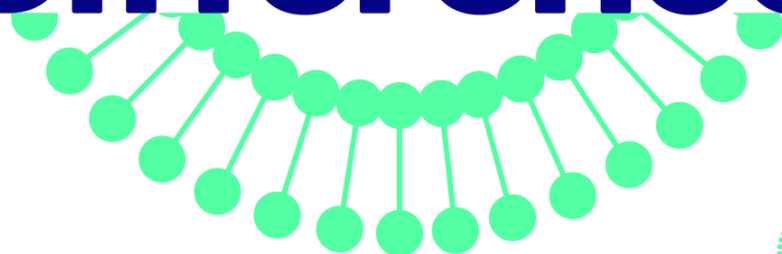
At the R&D Stage

Avanti will establish a Development Team to ensure the smooth development of your excipient and 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.



Discover the Difference



R&D Process:

- Synthetic process development
- Synthetic scale-up development (non-cGMP and cGMP)
- 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



Novel Excipient Process Development

Discovery

- Synthetic route scouting
- Elementary hazard assessment
- Target product specification

Stage 1

- Develop process & validation strategy
- Develop raw material specifications, CoA, IPCs, & reference standards
- Define impurity profile
- IND support

Stage 2

- Qualify GMP plant & equipment
- Validate analytical methods
- Qualify raw materials
- Process scale up & operational standards
- Refine development report & identify critical process steps

Stage 3

- Lockdown CPPs, PARs, & CQA
- Complete impurity profile
- Validate process & cleaning
- Full stability program

Commercial Process

Phospholipids

- 20+ catalog GMP phospholipids
- Lipid mixtures
- Natural product extracts

Lipid Adjuvants

- Lipid A derivatives
- 7 Current CDMO products

GMP Product Portfolio

Cationic Lipids

- 7 Current CDMO products

PEGylated & Neutral Lipids

- PEGylated lipids
- Functionalized PEG lipids
- Triglycerides
- Sterols
- 4 Current CDMO products

Why Choose Us?

Choosing Avanti for your cGMP contract manufacturing offers specialized expertise in lipid production and a strong commitment to quality and purity. Operating under strict cGMP guidelines, we ensure compliance with regulatory standards, which is crucial for pharmaceutical products. Our ability to provide high-purity lipids and customized solutions tailored to your specific needs makes us a reliable partner for both small-scale research and large-scale production.

We also excel in technical and regulatory support, assisting clients through the development and manufacturing process to ensure smooth project progression. With a proven track record of delivering high-quality products and services, and a focus on innovation, we aim to stand out as your trusted choice for cGMP contract manufacturing, offering confidence and peace of mind for your pharmaceutical and biotechnology projects.

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



From Research &
Discovery

Through Clinical Trials

To Commercialization

Contact Us Today!

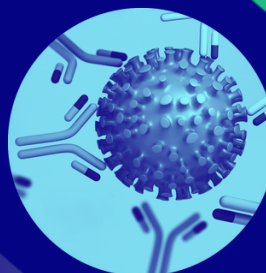
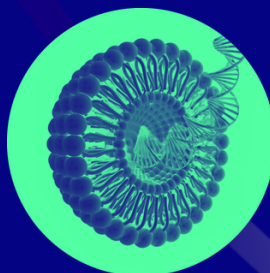
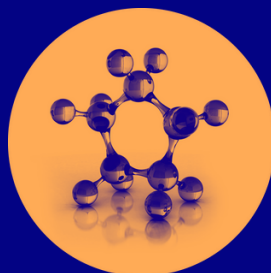


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