AMRI®
Albany Molecular Research Inc.

Drug Product Manufacturing
cGMP Liposomal Formulation Fill/Finish

With Albany Molecular Research Inc. (AMRI) as your Drug Product Manufacturing provider, you will benefit from years of experience working with – and scaling up – a variety of different liposomal formulations in our state-of-the art cGMP manufacturing facility.

We have successfully formulated Small, Unilamellar Vesicles (SUVs); Large, Unilamellar Vesicles (LUVs); Multilamellar Vesicles (MLV's); and oil-water double emulsion type systems utilizing a variety of equipment options and techniques. In addition, we have the ability to encapsulate small-molecule actives, proteins and peptides within the liposome dispersion successfully while maintaining critical process parameters, such as infusion rates, mixing rates, pressure and temperature.

Sterile Filtration of Liposomes

AMRI has worked to develop and optimize sterile filtration parameters specific to liposomal formulations where small scale studies are performed to determine membrane material compatibility and flux decay during sterile filtration.

For products which are not amenable to sterile filtration, AMRI Burlington has developed GMP aseptic formulation processes. To that extent, AMRI designed and built a Grade A Cleanroom for an aseptic liposomal process and was also able to develop and qualify an aseptic microfluidization process using a Microfluidics M700 commercial scale Microfluidizer processor. Similarly, AMRI developed an entirely disposable system which also maintains aseptic integrity during processing.

The AMRI Advantage:

- Expertise with a variety of liposome formation techniques
  - Thin film evaporation and rehydration
  - Ethanolic injection
  - Pure aqueous formulations/processes in tandem with a variety of techniques for mechanical sizing of the liposome including high shear homogenization and high pressure extrusion
- Experience with small scale, disposable ultra and diafiltration systems (UF/DF) and large scale GE skids for UF/DF using hollow fiber (capable of processing 100L or more to remove the organic solvent and free drug)
- Capable of producing registration lots for liposomal products, as well as scaling up processes for process-validation runs.

For inquiries, email us at: **clientservice@amriglobal.com**