

As part of its fully integrated global contract pharmaceutical service offering, AMRI provides aseptic formulation and filling. We support clients in pre-clinical through commercial scale production of liquid-filled parenterals, biologics and medical devices in vials, syringes and other custom containers.

Our Quality, Engineering and Manufacturing teams provide regulatorycompliant and innovative solutions to even the most demanding manufacturing challenges. Our areas of specialization include difficultto-process viscous and suspension products, microfluidization, homogenization, low-shear mixing and Quality Control Laboratory services.

Our state-of-the-art formulation and filling technologies offer safe and unique manufacturing processes customized specifically for our clients, as well as our patented BUBBLE-FREE FILLING[®], and have been FDA inspected for drug and aseptically-processed medical devices.

Whatever your needs, AMRI will assist you in finding the very best solution, and will work with you to achieve your production goals.

Expertise In

- Small and Large Molecules
- Proteins
- Liposomes
- Suspensions
- Viscous gels
- Emulsions
- Microfluidization
- Homogenization

Syringe Filling

Inova H3-5V

- Up to 100,000 units/batch. Validated to fill 1mL, 1-3mL, and 10mL syringes
- BUBBLE-FREE FILLING[®]
- 3-5 head positive displacement pump
- N2 purge capability

Inova SV-122

- Up to 20,000 units/batch. Validated to fill 1mL, 1-3mL, 5mL and 10mL syringes
- Disposable product pathway
- Variable depth stoppering
- 1-2 head positive displacement
- Off-line vacuum stoppering



Drug Product Manufacturing Aseptic Fill Finish

Vial Filling

Inova VFVM-3031

- 0.3mL to 100mL
- Up to 50,000 2mL units per batch
- Inline pre-gas purge
- Inline liquid fill
- Suction stopper placement
- Class 100 capping
- Low hold-up volume filling

Lyophilization

BOC Edwards Lyomax3

- Six product shelves
- Up to 11,520 2mL vials per batch
- 36 square feet of shelf area
- Two shelf interdistant settings (69mm or 140mm)
- · Lead/Lag circulating pumps (For shelves and condenser)
- Redundant systems (Compressors, vacuum pumps)

Hyaluronic Acid Expertise

- Medical grade
- Varied molecular weights
- Formulated solutions
- Customized packaging

Quality

Ensure client satisfaction by striving to provide our customers with the highest possible level of quality products, services, on-time delivery and courteous, professional communication.

Engineering

Dedicated to delivering engineering excellence. Our engineers provide the support functions and expertise to ensure compliance with current Good Manufacturing Practices and client requirements.



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