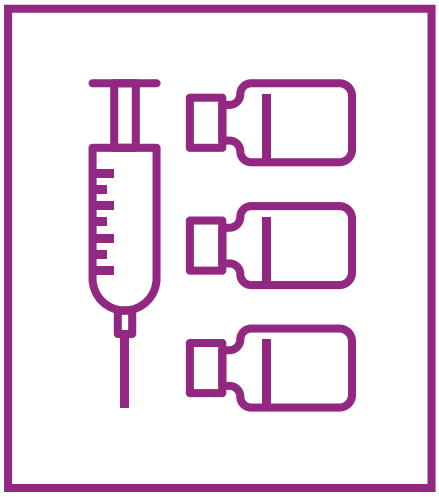
WE'VE GOT DRUG PRODUCT DOWN TO AN EXACT SCIENCE

OPTIMIZE THE PATH OF YOUR PROJECT FROM BENCH TO MARKET

Leverage our expertise and capabilities for your sterile drug product development and manufacturing objectives at any scale across early clinical through large-scale commercial. We provide a complete suite of services for all sterile dosage forms including injectable, nasal and ophthalmic product development and commercialization.



Drug Product

AMRI offers comprehensive capabilities and in-depth knowledge designed to meet any need through the entire life cycle of your sterile drug product.

INTEGRATED SERVICES FOR COMPLEX DRUG PRODUCT CHALLENGES

Bringing together many years of expertise in both developing and manufacturing sterile drug products, AMRI is a leading expert in the aseptic filling of drug product whether for simple solutions or the most complex challenges. Our capabilities include:

- Demonstrated track record with simple and complex liquid, suspension and lyophilized products
- Formulation development expertise that accounts for process and in-clinic requirements throughout the program
- Continuity of cGMP and scale supported by a single organization, minimizing tech transfer costs and timelines while retaining product knowledge
- Solving cGMP production challenges through seamless integration with scientists and process engineers
- State-of-the-art facilities and equipment with best-in-class containment procedures that enhance sterility assurance, regulatory compliance and operator safety

amri

Complex Science. Expert Solutions.

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Our complete suite of development and manufacturing services includes:

- Preformulation and formulation development (material sciences, formulation screening, excipient compatibility, solubility and stability enhancement, including in-use assesments)
- Lyophilization (thermal property mapping, cycle development, cycle optimization)
- Process engineering and GMP scale-up expertise for complex formulations such as viscous, liposomal and nanoparticulates
- cGMP manufacturing at any scale from 10 L to 2000 L into vials, syringes or dropper bottles
- Experience at handling proteins/peptides, hormones, steroids, controlled substances, highly potent and cytoxic compounds across complex formulations including liposomes, emulsions, suspensions, nanoparticulates and highly viscous liquid

Core Competencies and Technologies

- Biologics (liquid fill and lyophilized products, proteins, peptides, monoclonal antibodies, vaccines) and small molecules
- Viscous biopolymers
- Suspensions
- Liposomes, micelles and other nanoparticulates
- Microfluidization and high-shear homogenization
- Extrusion
- Cytotoxics and highly potent compounds
- Controlled substances
- Ultrafiltration/diafiltration skids
- In-process temperature control (jacketed glass and stainless steel vessels, wave mixers, jacketed systems for 3-D mixing bags)
- Disposable mixing systems

Filling and Storage Services

We provide flexibility in filling and storage, including:

- Vials, syringes and bottles
- Liquid and lyophilized (injectable, ophthalmic and nasal)
- Potent and nonpotent
- ICH stability storage

Ophthalmic Products

Our GMP manufacturing for topical and injectable ophthalmics includes:

- Dossier development for ophthalmic solutions and suspensions
- Final dosage forms including standard bottles, sterile multiuse bottles and prefilled syringes and vials

Formulation development for ophthalmics includes:

- Injectable and topical ophthalmic formulation development expertise
- Rheological assessment (flow property assessment)
- Selection of excipients for ophthalmic administration
- Stability and solubility enhancement techniques

Sterile GMP Manufacturing Facilities

*Sterile dosage form development services also available in Glasgow, Leon and Albany (US)

AMRI is a global contract research and manufacturing organization that has been working with the life sciences industry to improve patient outcomes and quality of life for more than 25 years.