COMMERCIAL MANUFACTURING

Drug product manufacturing
Scaling product from bench to market

Curia offers comprehensive development and manufacturing services to meet needs through the entire life cycle of your sterile drug product. Leverage our in-depth expertise and capabilities at any scale, from early clinical through large-scale commercial.

Integrated Services for Complex Drug Product Challenges

Curia's expertise in aseptic fill/finish, powered by decades of experience in manufacturing sterile drug products, helps you maximize the impact of your product.

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

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 assessments)
+ 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 or syringes
+ Experience at handling proteins/peptides, controlled substances, highly potent and cytotoxic compounds across complex formulations including liposomes, emulsions, suspensions, nanoparticulates and highly viscous liquid

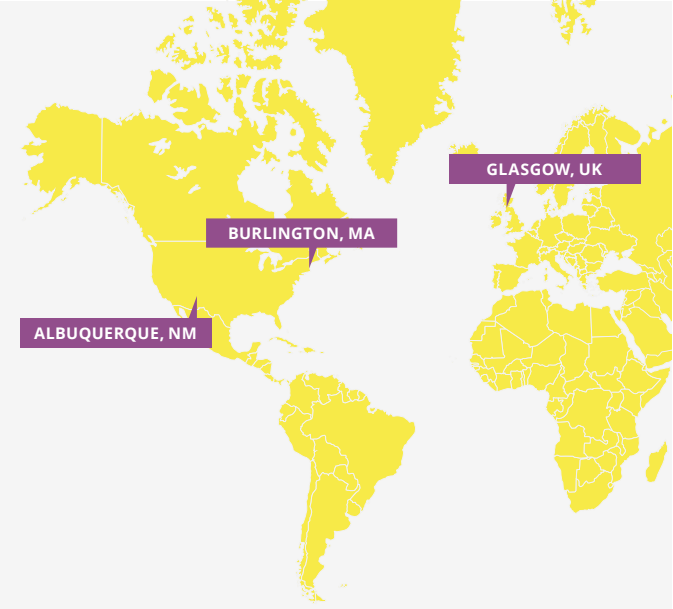
COMMERCIAL MANUFACTURING

Core Competencies and Technologies

Curia is an industry leader in the development and manufacture of DEA-controlled substances and derivatives.

+ 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 3D mixing bags)
+ Disposable mixing systems

Sterile GMP Manufacturing Facilities



Filling and Storage Services

We provide flexibility in filling and storage, including:

+ Vials and syringes
+ Liquid and lyophilized (injectable and nasal)
+ Potent and nonpotent
+ ICH stability storage

Curia, formerly AMRI, is a global contract research, development and manufacturing organization, offering products and services across the drug development spectrum to help our partners turn their ideas into real-world impact. We partner closely with pharmaceutical and biotechnology companies to boost business performance and improve patients' lives.

curia

NORTH AMERICA • EUROPE • ASIA

RESEARCH & DEVELOPMENT
LAB TESTING SERVICES
COMMERCIAL MANUFACTURING
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