

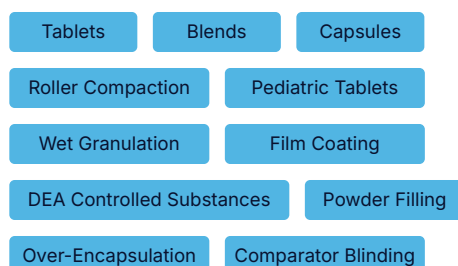
Drug Product Manufacturing

Robust, scalable solid dose and parenteral manufacturing equipment trains delivering confidence from clinical through commercial supply.



Alcami provides GMP manufacturing services tailored to match your development and approval timelines. We offer a comprehensive platform for pharmaceutical development with expertise in small and large molecules, lyophilized products, complex formulations, high potency compounds, and DEA-scheduled drugs. Our experienced teams in formulation, analytics, packaging, and distribution ensure seamless progress through the development process, overseen by personalized project managers, supporting optimal outcomes throughout your product's lifecycle.

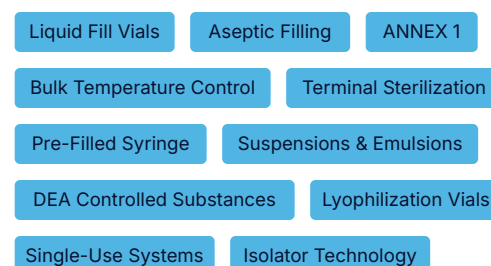
Solid Dose Capabilities (10 Flexible Suites)



Packaging

Bottles
Blisters
Vials
Pre-Filled Syringes
Carding & Walleting
Cartoning
Labeling
Trial Kit Assembly

Parenteral Capabilities (6 Fill Lines)



Labeling

Clinical Labeling
Clinical Trial Blinding
Commercial Labeling
Serialization & Aggregation

Storage & Shipment

Long-Term Storage
Cold Chain Solutions
Shipment Readiness

STERILE FILL-FINISH MANUFACTURING

CHARLESTON, SC

This 74,000 sqft, fully US- and EU-compliant site is DEA licensed and has been fully integrated with our Wilmington, NC packaging and distribution center for over 22 years.

Core capabilities:

Sterile solutions, suspensions, emulsions, and lyophilized drug product

Aseptic filling lines with isolator technology for filling liquid and lyophilized vials and pre-filled syringes

Terminal sterilization for vials

On site laboratory services specializing in biologics and small molecule testing

RTP, NC

This 32,000 sqft drug product manufacturing facility includes isolator manufacturing capabilities for liquid syringes, liquid and lyophilized vials, and is FDA and DEA compliant.

Storage temperatures: -80°C, -20°C, 5°C, controlled room temperature (CRT)

Lyophilization Cycle and Formulation Development

Development and manufacturing of DEA Schedule I-V products

FDA, EMA, MHRA, PMDA and GMP compliant

Talk to us.

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ORAL SOLID DOSE MANUFACTURING

Alcami's formulation development experts assist in solid-state characterization services, product development and lifecycle management including formulation changes and qualification of additional indications.

WILMINGTON: Specialized to manufacture oral solid dosage forms, Alcami's Wilmington, NC campus is arranged in flexible suites to support advanced and complex projects.

Core capabilities:

First-In-Human (FIH) to commercial	Tray and fluid bed dryers
Flexible GMP suites with cold chain and low humidity options	Powder in capsules, powder in bottles, powder in stick packs
High & Low Shear wet granulation	Compression and Encapsulation, hand and machine forming
Top spray granulation	Xceledose
Wurster Coating	Mini-tablets
Roller compaction and milling	Overencapsulation, Comparator Blinding
Blends up to 650kg, density dependent	Laser imprinting
Functional/non-functional film (aqueous-based) coating	DEA schedule I-V
Immediate and modified release	Accommodate projects up to Safebridge 3b with risk assessment

PACKAGING AND LABELING SERVICES

We also provide specialized expert support for **randomization and blinded clinical studies**, including placebo, comparator, and crossover studies, as well as reconciliation drug accountability, serialization, and destruction services as needed.

With the ability to accommodate preclinical through commercial lifecycles, our inherent flexibility allows clients direct access to a simplified supply chain. Alcami offers stand-alone pharmaceutical packaging through full development programs that can be integrated with manufacturing, stability storage, and analytical services.

Core capabilities:

First-In-Human (FIH) to commercial	Open and blinded labels and randomization
Solid dose bottling (30cc to 500cc round)	Serialization with three or four levels of aggregation available
Cold form and thermoform blistering lines	Temperature controlled and humidity monitored warehouse
Vial labeling and semi-automated secondary packaging (vial size 2 - 50mL)	Cold chain logistics
Pre-filled syringe labeling	Proven regulatory track record
Multi-lingual labeling	DEA schedule I-V
Manual packaging and clinical kitting	



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**Drug Product
Manufacturing**

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Drug Product Manufacturing
Laboratory Services
Pharma Storage & Services

Charleston, SC • Wilmington, NC
RTP, NC • The Netherlands, Europe
Clinton, TN • St Louis, MO
New England • Reno, NV