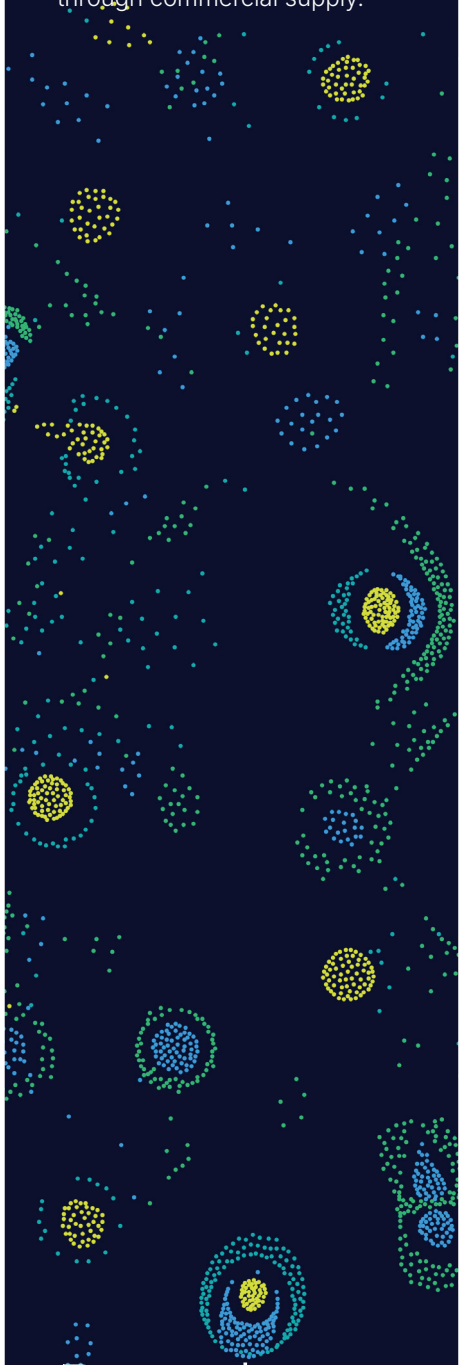
Drug Product Manufacturing

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



Beyond expectations.

alcami®

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)

- Tablets
- Blends
- Capsules
- Roller Compaction
- Pediatric Tablets
- Wet Granulation
- Film Coating
- DEA Controlled Substances
- Powder Filling
- Over-Encapsulation
- Comparator Blinding

Parenteral Capabilities (6 Fill Lines)

- Liquid Fill Vials
- Aseptic Filling
- ANNEX 1
- Bulk Temperature Control
- Terminal Sterilization
- Pre-Filled Syringe
- Suspensions & Emulsions
- DEA Controlled Substances
- Lyophilization Vials
- Single-Use Systems
- Isolator Technology

Packaging

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

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, PDMA and GMP compliant

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
- Flexible GMP suites with cold chain and low humidity options
- High & Low Shear wet granulation
- Top spray granulation
- Wuster Coating
- Roller compaction and milling
- Blends up to 650kg, density dependent
- Functional/non-functional film (aqueous-based) coating
- Immediate and modified release
- Tray and fluid bed dryers
- Powder in capsules, powder in bottles, powder in stick packs
- Compression and Encapsulation, hand and machine forming
- Xceledose
- Mini-tablets
- Overencapsulation, Comparator Blinding
- Laser imprinting
- DEA schedule I-V
- 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
- Solid dose bottling (30cc to 500cc round)
- Cold form and thermoform blistering lines
- Vial labeling and semi-automated secondary packaging (vial size 2 - 50mL)
- Pre-filled syringe labeling
- Multi-lingual labeling
- Manual packaging and clinical kitting
- Open and blinded labels and randomization
- Serialization with three or four levels of aggregation available
- Temperature controlled and humidity monitored warehouse
- Cold chain logistics
- Proven regulatory track record
- DEA schedule I-V

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Drug Product Manufacturing
Laboratory Services
Pharma Storage & Services

Charleston, SC • Wilmington, NC
RTP, NC • St Louis, MO
New England • Reno, NV