

DRUG PRODUCT DEVELOPMENT, MANUFACTURING, AND PACKAGING.

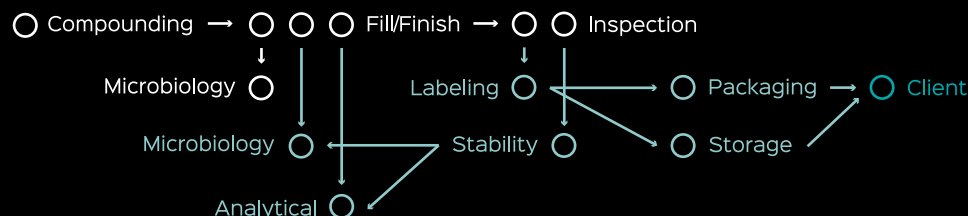


Alcami supports customized manufacturing services for oral solid dose and parenteral products from Compound to Clinic.®

PARENTERAL FORMS.

Alcami will exceed your small and large molecule manufacturing expectations and accelerate the progression of your project through its entire lifecycle. Our end-to-end service offering, coupled with a diverse portfolio of preclinical to commercial capabilities and our experienced quality team, provides a smoother route to launch your product.

PRODUCTION FLOW.



CAPABILITIES.

- Development and manufacturing of parenteral products for small and large molecules– proteins, peptides, antibody drug conjugates, and monoclonal antibodies
- Aseptic/sterile drug product processing
- Terminally sterilized pharmaceutical products
- Sterile solutions, suspensions, and emulsions
- Process development, optimization, and validation
- Homogenization with lyophilization cycle development
- Liquid fills with solvent based formulations
- Potent and highly potent compounds
- Visual inspections
- Automated filling
- Isolation capabilities for potent compounds
- In-house filter validation
- In-house extractables/leachables method development and testing
- Batch sizes up to 30,000 vials from 2mL to 50mL in sterile manufacturing
- US FDA, EU MHRA, and cGMP compliant manufacturing facility
- DEA compliant for Schedule 2, 2N, 3, 3N, 4, 5, and L1 compounds

ORAL SOLID DOSE FORMS.

Specialized to manufacture oral solid dosage forms, Alcami's Wilmington, North Carolina site supports preclinical production through commercial launch and supply. Our cGMP manufacturing technologies, including low/high shear granulation and spray/fluid bed drying capabilities, are arranged in flexible suites to support advanced and complex projects. Embedded within the manufacturing facility, our formulation development experts assist in product development and lifecycle management including formulation changes and qualification of additional indications.

PRINCIPAL OFFERINGS.

- Tablets
 - Immediate and modified release
 - B&D tooling
- Capsules
 - Powder blend and granulations
- Fully-automated powder in capsule and powder in bottle manufacturing
- Comparator blinding
- Wet granulation
- Roller compaction
- Film coating
- Over-encapsulation

CAPABILITIES.

- DEA compliant for Schedule 1, 2, 2N, 3, 3N, 4, 5, and L1 controlled substances in our manufacturing facility
- Flex suites for novel manufacturing processes
- Small volume product support with small lot sizes made as needed

TABLETS.

- Immediate release
- Sustained release
- Controlled release
- Orally disintegrating
- Minitablets

HARD SHELL CAPSULES.

- Powder blends
- Neat filled drug in capsule as low as 0.5mg
- Beads or minitables in capsules
- Over-encapsulation for clinical blinding

POWDERS.

- Blends in bottles for reconstitution
- Neat API bottle fills for Phase I clinical supplies



PACKAGING AND LABELING.

Alcami optimizes packaging and distribution capabilities by tightly integrating manufacturing services as part of our comprehensive service offering. We provide custom packaging, labeling, study kit assembly, and storage for worldwide research studies.



SPECIALIZED PACKAGING.

- DEA compliant for Schedule 1, 2, 2N, 3, 3N, 4, 5, and L1 controlled substances
- Potent compounds
- Temperature sensitive
 - Controlled room temperature
 - Refrigerated
 - Frozen
- Photosensitive
- Clinical labeling
- Drug return and destruction

SECONDARY PACKAGING.

- Carding and walleting
- Cartoning
- Labeling
- Pouching
- Trial kit assembly

PRIMARY PACKAGING.

- Bottles
- Blisters
 - Thermoform/Alu cold form
- Vials
 - Sterile
 - Liquid
 - Lyophilized
- Pouches

STABILITY SERVICES.

- ICH and custom storage conditions
- Sample control unit
- Analytical services

THE ALCAMI ADVANTAGE.

Your project deserves the most connected experts in the industry. Trust Alcami to accelerate your product through the clinic to commercial launch. Throughout our history, Alcami has manufactured a significant amount of oral solid dose and parenteral batches in both Wilmington, North Carolina and Charleston, South Carolina.



ABUSE-DETERRENT STUDIES.

Our scientists have experience developing formulations and designing and executing *in vitro* studies to fully characterize abuse-deterrent products.



SERIALIZATION.

The Alcami packaging team has successfully completed right-first-time packaging and shipment of serialized commercial batches– enhancing patient safety and supply chain security one barcode at a time.



NON-NEGOTIABLES.

Honesty



Integrity



Safety



Regulatory Compliance



Quality





OPERATIONS

Charleston, SC
Durham, NC
Edison, NJ
Germantown, WI
St. Louis, MO
Weert, Netherlands
Wilmington, NC

COMMERCIAL OFFICES

Cambridge, MA
San Diego, CA
Tokyo, Japan



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