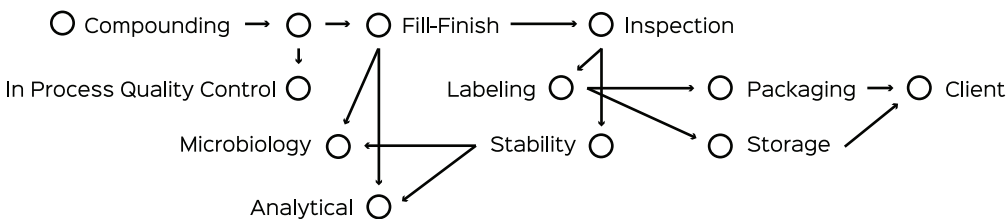


# DRUG PRODUCT DEVELOPMENT, MANUFACTURING, AND PACKAGING.

## 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, and monoclonal antibodies
- Aseptic / sterile fill-finish processing
- Terminally sterilized pharmaceutical products
- Sterile solutions, suspensions, and emulsions
- Process development, optimization, and validation
- High shear processing, homogenization, and microfluidization
- Lyophilization development and manufacturing
- Liquid fills with solvent-based formulations
- Single-use systems
- In-line monitoring
- Visual inspection
- Automated filling
- Isolation capabilities for potent compounds
- In-house extractables / leachables method development and testing
- Vial sizes from 2mL to 50mL with liquid or lyophilization capabilities
- Batch sizes up to 330L and 50,000 vials  
\*1,000L formulation capability in 2021
- FDA, EMA, MHRA, JP, and cGMP-compliant manufacturing facility
- DEA compliant for Schedule 2, 2N, 3, 3N, 4, 5, and L1 compounds

# ORAL SOLID DOSAGE FORMS.

Specialized to manufacture oral solid dosage forms, Alcami's Wilmington, NC site supports preclinical production through commercial launch and supply. The facility's cGMP manufacturing technologies, including low shear, high shear, and spray granulation and fluid bed drying capabilities, are arranged in flexible suites to support advanced and complex projects. Alcami's 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 manufacturing
- Comparator blinding
- Wet granulation
- Roller compaction
- Film coating
- Over-encapsulation

## CAPABILITIES.

- First in human accelerated development
- Design of experiments
- Criticality of materials and processes
- Flex suites for novel manufacturing processes
- Product life extensions
- Small volume product support with small lot sizes made as needed
- FDA, EMA, MHRA, JP, and cGMP-compliant manufacturing facility
- DEA compliant for Schedule 1, 2, 2N, 3, 3N, 4, 5, and L1 controlled substances in our manufacturing facility

## TABLETS.

- Immediate release
- Sustained release
- Controlled release
- Delayed release
- Orally disintegrating
- Fixed dose combinations
- Minitablets
- Flavored chewables

## 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

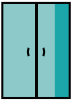
## POWDERS.

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



# PACKAGING AND LABELING.

By tightly integrating manufacturing services with its packaging and distribution capabilities, Alcami has optimized its comprehensive service offerings, including custom packaging, labeling, study kit assembly, and storage for research studies, worldwide.



## PRIMARY PACKAGING.

- Bottles
- Blisters
  - Thermoform / Alu cold form

## SECONDARY PACKAGING.

- Carding and wadding
- Cartoning
- Labeling
- Pouching
- Trial kit assembly
- Serialization

## SPECIALIZED PACKAGING.

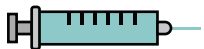
- DEA compliant for Schedule 1, 2, 2N, 3, 3N, 4, 5, and L1 controlled substances
- Potent compounds
- Temperature sensitive
  - Controlled room temperature
  - Refrigerated
  - Frozen
- Photosensitive
- Tamper evident
- Clinical labeling
- Drug return and destruction

## STABILITY SERVICES.

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

## 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.



## THE ALCAMI ADVANTAGE.

Your project deserves the most connected experts in the industry. Our manufacturing, development, and quality teams work in close collaboration to ensure that projects have a successful transition through every phase of their lifecycle.

[alcaminow.com](http://alcaminow.com)  
1-800-575-4224