Company Overview

Alcami offers a world-class end-to-end outsourcing opportunity as well as individualized development and manufacturing services.

The Alcami Advantage

Alcami specializes in all phases of pharmaceutical development — from critical preformulation studies to commercial product lifecycle management. Over the past 30 years, Alcami has supported more than 500 Investigational New Drug (IND) filings and over 50 New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA) and New Animal Drug Applications (NADA). Our fully integrated, comprehensive development services are well established and ready to help our clients get the most out of their portfolios.

Principal Offerings:

- Formulations to improve pharmacokinetics
- Reducing development timelines by as much as 10%
- Online Services for compendial raw materials testing with release in 10 business days or less
- 8,200 cubic feet of stability storage with full ICH and custom conditions
- Strong compliance record, including DEA controlled substances. Routinely inspected by FDA, MHRA, and EMA
- Developed formulations, analytical methods and manufactured products in more than 600 U.S. and EU regulatory filings
- Wide range of tablet manufacturing capabilities, as well as powder-in-capsule and powder-in-bottle
- From a few hundred to 50,000 vials per batch

1,000
Number of employees

740,000
ft^2 across U.S. & Europe facilities

82,000
ft^3 of stability storage space

600
U.S & EU regulatory filings

50,000
Vials per batch

500
Investigational New Drug (IND) Filings

Connected At Every Level

Alcami offers individualized development and manufacturing services that can be integrated for a less fragmented and faster pathway for products.

Connected From Start To Finish

Alcami is the new CDMO you already know. We offer a world class end-to-end outsourcing opportunity as well as individualized development and manufacturing services that can be integrated for a less fragmented and faster pathway for products through the clinical toward commercialization. With a flexible and responsive approach, you benefit from our highly integrated operations. Our expertise ensures the best possible outcome for your product at every level.

AAIPharma Services Corporation and Cambridge Major Laboratories, Inc. have joined to form Alcami, a world-class supplier of comprehensive pharmaceutical development and manufacturing services headquartered in Wilmington, NC. With nearly 1,000 employees operating at seven sites in the United States and Europe, our combined capabilities include API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging and stability services.

Our Approach

Evaluations and Proposals

Alcami's collaborative approach starts at the earliest opportunity; at the evaluation stage when RFP development, initial discovery and dialogue can reveal a drug product's true potential and set the stage for its future success. We have a well-established and proactive evaluation team with the experience and resources to help fashion a customized proposal tailored to meet the needs of all involved and deliver a highly successful program. Connecting closely with our customers is something we've become really good at and all our offerings remain world-class. Experience has helped Alcami simplify this process and make it easy to structure a singularly effective proposal that has the backbone to support your program's strategic goals and deliver its therapeutic outcomes.

Project Management

At Alcami we understand that project management is a critical factor in your success. Projects are administered personally, holistically and proactively to assure the best results. Our philosophy seamlessly aligns programs with operations, quality, regulatory and compliance and assures that no matter where one enters the process, the experience and the results are the same. Through care, precision, and diligence we make this possible. Alcami makes it easy for our partners to bring their products through the clinic to commercialization. We embrace an approach that integrates program, project and process in a unique and highly effective way and where a product's potential is turned into reality day-after-day.

Regulatory Affairs / Quality Assurance

Supporting clients and their projects worldwide —

- We support our client's projects in over 35 countries around the world.
- We have successfully been inspected by regulatory inspections from the TGA, PMDA, MHRA, Health Canada, MPA, IMB, FDA, and more.
- All of our facilities are in good standing with all regulatory authorities, including DEA, EPA, OSHA, etc.
- The Quality / Regulatory staffing has increased by over 100% in the last 5 years.
- Our Quality Management System and supporting analytical processes are almost 100% electronic, to allow for more immediate access to the data that is relevant to your needs.

Quality, EH&S and Compliance

At Alcami, we are committed to achieving World Class safety performance. In 2015, we demonstrated this commitment to operational excellence by implementing strategies that resulted in a total recordable injury rate (TRIR) of 1.38 (industry average: 2.1) and a reduction in our Lost Time Injury Rate (LTIR) of 0.2 (industry average: 0.8), well below the pharmaceutical industry average.

We meet all applicable local, state and federal regulatory requirements, including current GMPs and country guidelines for the U.S., Canada, EU and EU Member State regulatory bodies (e.g., EMA, MPA, IMB). We also incorporate international standards as part of the Quality Management System and meet expectations established by the USP, EP and JP. We comply with all regulations and standards, including those regarding controlled substances (DEA), radioactive materials (NRC), environmental protection (EPA), child-resistant container-closures (CPSC) and employee safety (OSHA).

Our Commitment

We are committed to building a close personalized connection with our customers where we collaborate intellectually, scientifically and philosophically. This relationship is cultivated from the onset to foster transparency and trust, on a foundation of communication, flexibility and creativity. Alcami is committed to connecting our customers and partners to the resources and capacity they need to assure the best possible outcomes for their products at every level.

Drug Development

Analytical Services

Assuring robust methods that can be transferred throughout the world.

- Analytical Development and Validation for Small Molecule
- Biotech, Large Molecule, Analytical Development and Validation
- Physical Chemistry and Material Characterization
- Stability Storage and Analysis
- Compendial Raw Materials Testing

Formulation Services

Proven know-how and timeliness for every development project.

- More than 300 compounds formulated over 30-plus years
- Oral Solid Dose Development
- Parenteral (both Liquid and Lyophilized) Formulation Development
- Oral Drug Delivery Technologies

Microbiological Services

- Microbial identification by MicroSEQ (R)

Manufacturing & Packaging

API Manufacturing

- Kilograms to multi-tons cGMP production
- Up to 2000 gallon scale
- State-of-the-art isolation and containment equipment
- Scalability across all sites driven by robust process development, DOE system modeling, engineered solutions and technology alignment
- cGMP Kilo lab up to 2000 gallon reactor suites
- Expert level RFQ assessment

Drug Product — Oral Solid Dose

- Batch sizes ranging from 200g of API for Phase I powder in capsules on the Xcelodose to large scale commercial tablet batches up to 650kg
- Potent Compound Manufacturing
- Dry Blends, Roller Compaction, Wet Granulation (Low/High Shear and Spray), Film Coating, Tablet and Capsule Manufacturing
- Flex Suites for Novel Manufacturing Processes

Drug Product — Parenteral

- Sterile Products for Small Molecules and Biotechnology, including Proteins, Peptides, Monoclonal Antibodies, Drug Conjugates and other Large Molecules
- Batch Sizes from 220mL up to 400L
- Aseptic Filtration/Filling, Terminal Sterilization and Lyophilization
- Filter Validations and Extractables/Leachables.

Packaging Services

- Custom Packaging, Labeling and Kitting for Clinical Trial Supplies
- Special Packaging Needs — square bottles, blisters, cartons, vials, ancillary supplies, concomitant medications, cases and cachets
- Temperature and Humidity Controlled Storage
- Temperature Monitoring and Validated Shipment Configurations

Support Services

Our in-house expertise in Regulatory Affairs and Quality Assurance can support your projects, inspections and filings.

- Quality Assurance
- Regulatory Affairs
- Stability Management

To meet client needs around the world, Alcami has state-of-the-art facilities at strategic locations in the United States and Europe.

Alcami offers all phases of pharmaceutical development for small and large molecules through two laboratories located in Durham and Wilmington, North Carolina. These facilities have supported more than 500 investigational New Drug (IND) filings and over 50 NDAs, ANDAs and NADAs since 1985.

Two cGMP API facilities in Germantown, Wisconsin and Weert, Netherlands support Alcami's process development/scale-up and clinical and commercial supply for customers worldwide. The Weert facility also serves as the company's Center of Excellence for Solid State Chemistry.

Regional cGMP analytical laboratories in St. Louis, Missouri, Wilmington, North Carolina and Edison, New Jersey provide comprehensive analytical testing solutions for Alcami customer's new drug entities and biopharmaceuticals, as well as generic drugs, chemicals and animal health, and medicated consumer health products.

Alcami's cGMP drug product manufacturing facilities support preclinical, clinical and commercial supply. Our Charleston, South Carolina facility is focused on processing parenteral products while the Wilmington, North Carolina facility is dedicated to solid oral dose manufacture. Both are fully integrated with Alcami's packaging and distribution center.

alcami®

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