



Protect Your Brand™ It's That Simple

Protect Your Brand™

Is a unique offering designed to support pharma-biotech companies pursuing a dual sourcing strategy. Under this program, Alcami will support tech transfer and validation of products in advance of potential manufacturing needs without any long-term commitment or minimum annual volume. It's that simple. This service can be used for drug substance, drug product and for clinical supplies, launch quantities, commercial supply. Alcami can be ready quickly to bridge unexpected gaps in your critical supply needs.

Protect Your Brand™, Secure Your Supply Chain

As supply chain complexity grows, risks continue to mount. From quality issues and drug shortages to warning letters and natural disasters, today's risks are significant and supply disruptions can be catastrophic. Alcami makes securing your supply easier than ever with Protect Your Brand™.

- Technology Transfer start within 1 month of inquiry
- No Annual Purchase Obligation
- No Long Term Contract
- Annual Product GAP Assessment
- Ongoing Readiness and Emergency Responsiveness
- Clinical and Commercial Supply
- Drug Substance, Drug Product and Packaging
- Biologics and Small Molecules

The Alcami Advantage

When developing a dual sourcing strategy, validation of processes with a trusted and reliable supplier, like Alcami, protects against supply chain disruptions.

- Broad in-house technical and regulatory expertise
- Innovative solutions for timelines and technical challenges
- Excellent track record of regulatory compliance across numerous agencies
- Full service, integrated CDMO who works on >200 molecules annually
- Flexibility and agility to respond to your needs quickly
- Successful CDMO approval for all filings to date
- State of Alcami Readiness™ Proprietary Scoring System

Complete Offerings From Start to Finish

Protect Your Brand™ offers three distinct dual supply solutions to prevent disruptions from occurring at the earliest concept through to post-commercial production.

Concept to Clinic

Formulation Process

- Raw Material Vendor Qualification
- Methods Transfer Report
- Clinic Ready Product
- IND Update Support
- Product GAP Assessment

Commercial

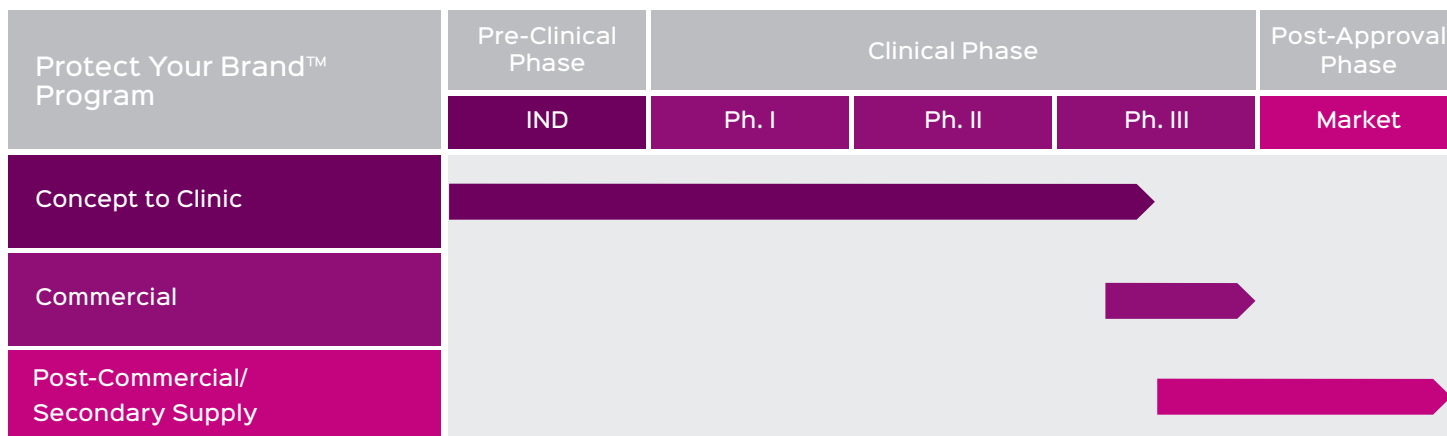
Scalability Stability

- Raw Material Vendor Qualification
- Methods Transfer Report
- Registration Batches for Filing
- Regulatory Filing Support
- Product GAP Assessment

Post-Commercial/ Secondary Supply

Supply Chain Security Line Extension

- Raw Material Vendor Qualification
- Methods Transfer Report
- Validation Batches for Filing
- Regulatory Filing Support
- Line Extension Support
- Product GAP Assessment



Assess Your Risk, Assign Our Readiness

All products are unique and every process carries its own risks. Protect Your Brand™ allows you to determine the ideal State of Alcami Readiness™. By responding quickly, Alcami can minimize the effects of a supply disruption, helping to prevent shortages and delays. We do this by using our proprietary state of Alcami Readiness™ scoring system and cover it in our annual state of readiness meeting.

Annual State of Readiness Meeting Topics:

Inputs:

Client defines desired Process

GAP Assessment of the Defined Process

- Technical Review of Process for Facility Fit
- Review of Analytical Methods and Fit for Purpose
- Review of Batch Records for State of Readiness
- Regulatory Change/Process Validation Assessment
- Supply Chain/Vendor Status Assessment
- Trending of available Stability Data

State of the Product

- Filing Status
- Demand Profile

Outputs:

- Current Risk Level and Readiness Summary
- Alcami provides strategy for each State of Alcami Readiness™ level
- Alcami and Client determine desired State of Alcami Readiness™ level
- Execute plan to reach desired State of Alcami Readiness™ level

State of Alcami Readiness™ Proprietary Ranking System assesses:

Readiness of:

- Raw materials and Vendor status
- Test methods and specifications
- Process and Facility Fit

Risk Factors:

- Client's Current Situation
- Product Phase
- Capacity Needs
- Client Supplied Material Availability



Connected At Every Level

AAI Pharma 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.

Company Snapshot

- Combined staff of nearly 1000
- 740,000 square feet across U.S. and European facilities
- State-of-the-art technology and infrastructure
- FDA and EU compliant operations
- DEA-licensed for controlled drug products

Protect Your Brand™

Protect Your Brand™ is a dual-source supply chain solution that's there when you need it most. Alcami's expertise in tech transfer and process validation combine with a unique, no-commitment approach to offer security and peace of mind in an increasingly complex global supply chain.



- Drug substance & drug product
- Clinical and commercial supply
- No annual purchase obligation
- No long term contract



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