SOLID STATE.

Alcam leverages its solid state chemistry expertise to design APIs with PhysChem characteristics for optimal formulation and drugability.

CAPABILITIES.

- Polymorph study
  - Selection and process control
  - Salt screening and selection
- Process development
  - Range finding design of experiments
  - Metastable zone width
- Particle habit engineering
  - Control of particle size and shape
- Preformulation
  - Dissolution rate
  - Excipient compatibility
- Crystallization study
  - Isolate and purify stable solids
- PhysChem characterization
  - Material identification
  - Stability
- Solubility determination
  - In production solvents and buffer solutions

INTEGRATED CAPABILITIES CAN SHORTEN TIMELINES BY 60%.
HIGH-POTENCY API DEVELOPMENT AND MANUFACTURING.

The increasing use of highly potent active pharmaceutical ingredients (HPAPIs) in new drug development candidates has created a tremendous demand for high containment development and production capabilities.

To meet this industry need, Alcami has invested significantly in the enhancement of its API manufacturing and development campus with expanded state-of-the-art HPAPI development and manufacturing suites, capable and qualified for controlling below 30ng/m³ exposure limits.

STATE-OF-THE-ART FEATURES AND SUPPORT.

- Primary containment and engineering controls for nanogram-level containment
- Dedicated utility and support systems for superior reliance and control
- Expert quality, hazard risk assessment, and mitigation support
- Full development and QC support
- Small molecule chemistry from gram to multi-kilo batch sizes

PROCESS CAPABILITIES.

- Small molecule chemistry from gram to 10kg batch sizes
- Distillation, cryogenic, and hydrogenation
- Filter isolation, drying, and packaging
- Versatile enclosed processing space for expanded portable capabilities

PROCESS CHEMISTRY.

Alcami provides phase-appropriate development from route scouting through full commercialization. Our experienced technical team combines their diverse and rich scientific background with Quality by Design principles to develop a comprehensive control strategy that ensures a readily scalable process in the cGMP manufacturing environment. From initial project onboarding until the final product is complete, our development and manufacturing teams are connected at every level.

SOLUTIONS FOR YOUR CMC CHALLENGES.

- Optimization of high dilution / low yield throughput issues
- Removal and control of heavy metals
- Removal of hazardous and / or high cost reagents
- Elimination of process chromatography
- Intermediate and API crystallization controls
- Optimization of equivalent loadings
- ICH Q11 defense of
  - Regulatory starting materials
  - Fate and tolerance of impurities
  - Critical quality attribute control and specification setting
  - Proven Acceptable Ranges (PAR) and Critical Process Parameters (CPP)
  - Impurity structural assessments
API DEVELOPMENT
AND MANUFACTURING.

Alcami’s Center of Excellence for API development and manufacturing is located within our state-of-the-art cGMP facility in Germantown, WI. From early preclinical through launch and commercial production, the site’s API development and manufacturing services and capabilities will get your product to market faster. The facility’s wide range of technologies include plant-scale hydrogenation and cryogenics.

FULL LIFECYCLE SUPPORT SERVICES.

<table>
<thead>
<tr>
<th>Preclinical Phase</th>
<th>Clinical Phase</th>
<th>Post Approval Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigational New Drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route development</td>
<td>Phase I</td>
<td>Market</td>
</tr>
<tr>
<td>Process research &amp; development</td>
<td>Phase II</td>
<td></td>
</tr>
<tr>
<td>Solid state chemistry</td>
<td>Phase III</td>
<td></td>
</tr>
<tr>
<td>Process optimization API scale up</td>
<td>API production</td>
<td></td>
</tr>
<tr>
<td>Preformulation development</td>
<td>Formulation development</td>
<td></td>
</tr>
<tr>
<td>Formulation development</td>
<td>Tech transfer / scale up</td>
<td></td>
</tr>
<tr>
<td>Clinical trial materials production, packaging, &amp; distribution</td>
<td>Process design &amp; validation</td>
<td></td>
</tr>
<tr>
<td>Process design &amp; validation</td>
<td>Registration batch mfg</td>
<td></td>
</tr>
<tr>
<td>Analytical development, qualification, &amp; validation</td>
<td>Analytical support quality control testing</td>
<td></td>
</tr>
<tr>
<td>Stability services</td>
<td>Commercial mfg</td>
<td>Next gen process</td>
</tr>
<tr>
<td>Regulatory support</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THE ALCAMI ADVANTAGE.

Whether you are a small start-up or a large enterprise, your project deserves the most connected technical 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.

NON-NEGOTIABLES.

- Honesty
- Integrity
- Safety
- Regulatory Compliance
- Quality

alcaminow.com
1-800-575-4224