

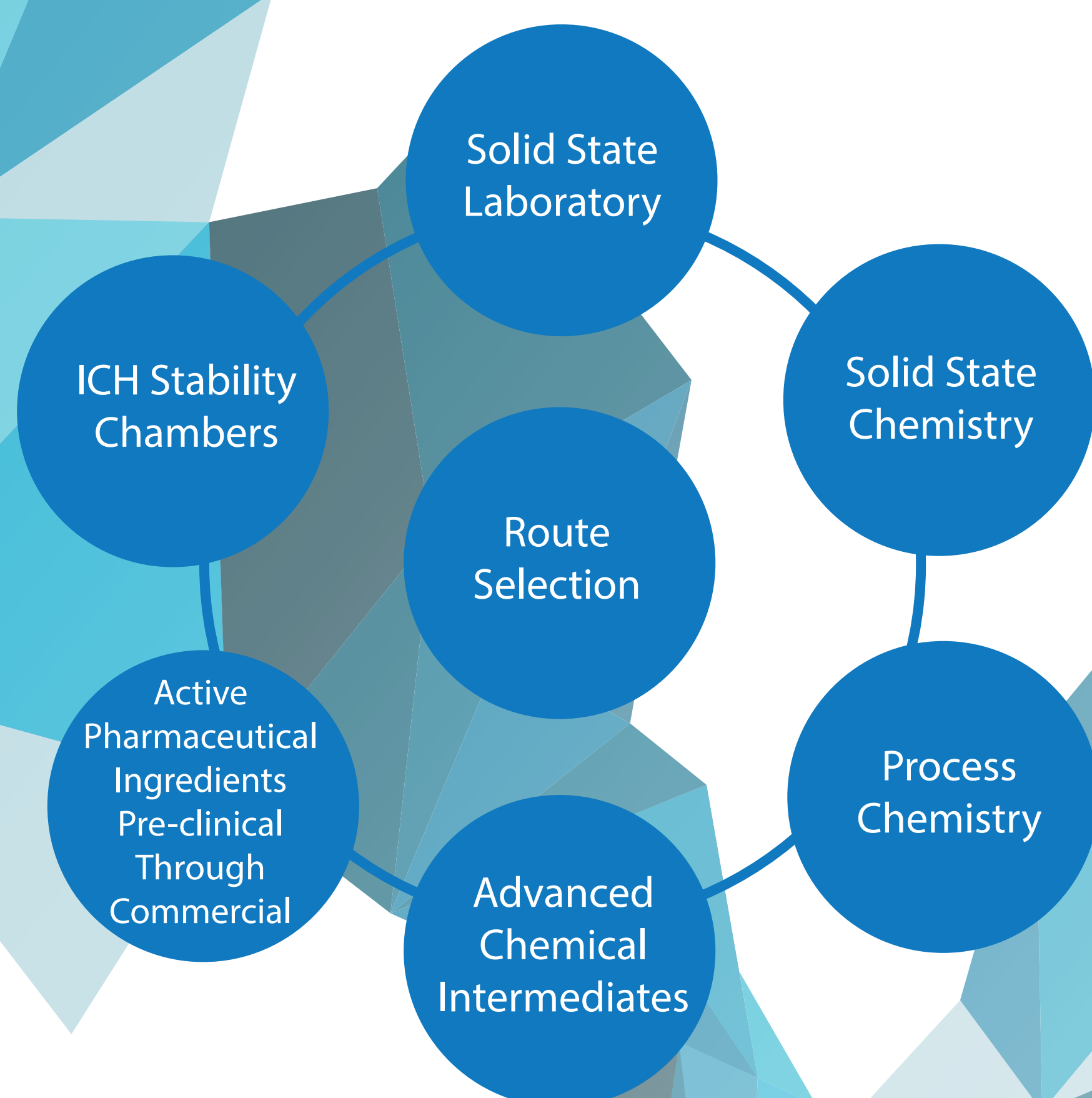
API Manufacturing and Development



Alcami's US API development center is housed in a state-of-the-art 5,575 square meter cGMP facility. The site is fully equipped to support development and manufacturing from kilo to ton scale, including plant scale hydrogenation and cryogenics (-90C). Reactors from 50L to 8000L with contained handling and experience across a very wide range of chemistries.

Alcami's European development center is located in Weert, Netherlands. The Weert facility is a 12,500 square meter site specializing in process research and development, with extensive analytical capabilities including a state-of-the-art Solid State Laboratory. The FDA inspected facility houses fully isolated pilot suites with reactors of up to 1000 liter, and is fully cGMP and ISO 14001 certified. The team is particularly experienced in early clinical CMC programs, and has helped many clients globally transition from preclinical studies into the clinic.

Process chemistry is the foundation of our API business. Alcami is aware that academically advanced scientists are essential to provide rapid and robust chemistry services to successfully support early preclinical quantities through full production at plant scale. Therefore, we have established an experienced core of Ph.D. scientists to develop robust chemistry process controls. When combined with the engineering design controls from our process engineers and process characterization and detection controls developed by Alcami's analytical scientists, your process will scale up right the first time. Because our development teams follow a project from the lab into the plant, we have the expertise to troubleshoot any possible issues that may arise during the scale-up phase.



Principal Offerings

- Kilograms to multi-tons cGMP production
- Broad CMC management and technical expertise
- Expert level RFQ assessment
- Up to 7570 liter 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
- Advanced EHS systems with a focus on industrial hygiene
- Significant new Investments in state-of-the-art equipment and facilities
- State-of-the-art Solid State/ Crystallization development lab
- Excellence in analytical chemistry - access to more than 200 analysts within Alcami

