Our Science-Forward Approach to API Development and Manufacturing

Cambrex's drug substance services are designed to help you advance your API with confidence, from early process development to commercial readiness.

We have an accomplished team of chemists and process engineers, a unique, science-led project management approach and a network of tightly coordinated sites to oversee all of your API development and manufacturing needs, including:

IND Enabling Services
Early Clinical API Development & Manufacturing
Solid State Chemistry
Late-Phase API Scale-Up & Technology Transfers
Continuous Flow Development & Manufacturing
Peptide Development & Manufacturing
Controlled Substance Development & Manufacturing
Highly Potent API Manufacturing
Biocatalysis Development

Our Approach

Determining the shortest, most economical path from investigational new drug (IND) to commercial launch is no easy feat. Our greatest strength is the ability to take especially challenging processes — either because of safety issues, poor yields or scalability concerns — and make them commercially viable.

Unlike at many CDMOs, our teams work beyond their individual sites, often collaborating with Ph.D.s and chemists across the Cambrex and Snapdragon Chemistry networks. We're here to help answer the myriad of questions and challenges that arise as you move your custom small molecule API development projects forward.

IND Enabling Services

Cambrex offers full CMC support for your IND application, from process chemistry and drug substance manufacturing all the way through formulation development and drug product manufacturing. Throughout the entire process, our analytical and manufacturing teams provide quality analysis and development of your program to ensure you meet your milestones. With process chemistry, drug product and analytical experts collaborating under the same roof in Longmont, Colorado, we ensure that your molecule has its best chance at success.

To help you meet strict IND requirements and accelerate the filing process, we provide all supporting analytical data (specifications and release data) for raw materials, intermediates and APIs. We also provide all master batch records and a certificate of GMP stating that we manufacture our APIs according to industry standards.

Early Clinical API Development & Manufacturing

Cambrex, enhanced by Snapdragon's world-class, collaborative problem solving capabilities, can help you optimize API drug development processes. Snapdragon scientists and engineers, working in state-of-the-art laboratories and leveraging advanced software and equipment, painstakingly pursue scalable synthetic processes for clients. We take pride in being able to "crack the code" on chemical development in a way that others can't, and we don't rest until your molecules are thoroughly characterized and your processes are repeatable, reliable and ready for production.

Solid State Chemistry

Understanding the physical properties of an API is critical in the development of a solid dosage form. During early development, the goal is finding a suitable solid form to enable a rapid progression to the next development milestone. In later phases of development, the focus shifts to identifying the optimal solid form for commercialization, as well as finding additional solid forms for intellectual property protection.

Cambrex offers solid phase screening and crystallization development programs to optimize the physical stability of your API, develop a more bioavailable formulation or overcome other solid state development challenges. Additionally, we offer a specialized crystallization screening platform for the discovery of crystalline forms of peptides and proteins.

Late-Phase API Development & Technology Transfers

As molecules progress, we help to create more cost-effective, robust and safe processes to manufacture your active ingredient for pilot and commercial production. Cambrex excels at turning early routes into commercially viable manufacturing routes during the drug development lifecycle.

We are structured to oversee custom small molecule process development from early clinical phase to commercial production, and we offer a flexible manufacturing landscape, with small-, mid- and large-scale facilities designed to support customized solutions and seamless transfer of technologies.

Continuous Flow Development & Manufacturing

While agnostic to our client's process development approach, we have unique expertise in completing multiple synthetic steps in one continuous flow process across a broad set of reactions and conditions. We leverage our advanced capabilities in autonomous process development and reactor platforms to deliver robust and scalable chemistry solutions for your toughest problems.

Innovators that can harness flow technology while applying artificial intelligence and machine learning early in the development process will have a decisive, lasting advantage over competitors as the technology enables important productivity, efficiency and speed enhancements.

Peptide Development & Manufacturing

Snapdragon Chemistry has developed a new liquid-phase peptide synthesis (LPPS) technology that utilizes traditional active pharmaceutical ingredient (API) batch reactors and continuous flow, obviating the dependency on specialized, solid-phase reactors. This new LPPS technology materially reduces solvent demand and the need for excess reagents compared to standard solid-state peptide synthesis processes.

The LPPS technology supports peptides up to 12 residues long, while larger peptides are then assembled in liquid phase, using a convergent fragment coupling approach. Processes developed with LPPS technology can be scaled in the same way as traditional small molecules.

Controlled Substance Development & Manufacturing

Navigating the stringent regulations surrounding controlled substance manufacturing requires specialized expertise. Cambrex is one of the few companies licensed to import narcotic raw materials at commercial scale. Our experienced team has expertise in manufacturing highly potent compounds for pain management, addiction treatment, obesity control, neurostimulants, ADHD and benzodiazepines.

We hold US Drug Enforcement Agency (DEA) licenses for process research, development, manufacturing and importation of Schedule II to IV controlled substances, and we have been successfully manufacturing highly potent compounds since 2005. Cambrex maintains Drug Master Files (DMF) for more than 20 controlled substance APIs.

Highly Potent API Manufacturing

We offer extensive experience developing and manufacturing high-potency APIs and compounds, including immunosuppressants, cytostatics/protein kinase inhibitors, ultra-potent cytotoxic drug substance, drug linkers, PEG and cyclodextrin polymeric conjugations and toxins for antibody drug conjugates (ADCs).

At our High Potency Development Center (HPDC) in Charles City, Iowa — a controlled-access facility with barrier isolation, airlocks and cascading air differentials equipped to handle low ng/m3 occupational exposure limits (OELs) — we can develop a range of HPAPIs, including compounds classified as ultrapotent.

Biocatalysis Development

Our biocatalysis development services provide customers with highly pure regio-, chemo- and enantioselective compounds when compared to traditional chemical synthesis. Benefits can range from shorter synthetic and alternate routes to biodegradable reagents and solvents, high-conversion, yield and enantiomeric excess while avoiding high enzyme and cofactor costs and reducing typical side reactions, meaning fewer by-products and impurities.

Our team of experts can custom-develop processes, design and optimize routes and provide R&D screening services using our proprietary library of more than 600 enzymes.

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance development and manufacturing across the entire drug lifecycle, as well as comprehensive analytical and IND enabling services.

With over 40 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, liquid-phase peptide synthesis, solid-state science, material characterization, and highly potent APIs.

Scan to connect with our experts.

Our scientists specialize in making connections. Start a conversation today and experience what it's like to work with a collaborative CDMO.