Analytical Services that Accelerate Drug Development and Commercialization

When you need a trusted partner to help advance your molecule through development and testing, you can count on Cambrex to help you find the most efficient path to a high-quality solution.

Our analytical services encompass best-in-class chromatographic, spectroscopic and mass spectrometric solutions, enabling us to deliver rapid method development for small molecules, large molecules and complex synthetics. Services include:

IND Enabling Services
Analytical Testing
Solid State Chemistry
Reference Standards Management
Stability Testing & Storage
Microbiology

Our Approach

Rigorous, effective analytical testing is key in the drug development and manufacturing lifecycle. Because this testing is used to verify control of drug chemistry, it can help identify barriers that prevent movement to the next phase in the development process. That's why it's critical to have efficient, accurate and high-quality analytical support for your testing requirements.

When you need a partner to overcome challenging test methods — or challenging molecules — you can rely on the Cambrex team. We offer a broad range of analytical testing services that extend across every phase of drug development.

Unlike many CDMOs, our teams work beyond their individual sites, often collaborating with Ph.D.s and chemists across the Cambrex, Snapdragon Chemistry and Q1 Scientific networks. We're here to help answer the myriad of questions and challenges that arise as you move your 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.

Analytical Testing

At Cambrex, you can rely on our extensive portfolio of analytical development solutions and testing services to rapidly advance your molecule for the greatest chance of success. In our more than 211,000 sq ft of combined laboratory space, we have a vast range of capabilities in analytical instrumentation and advanced detection, including high-throughput chromatographic column screening, enabling us to generate high-impact development datasets with efficiency for our clients. Analytical testing services include:

- Method Development and Validation
- Release and ICH Stability Testing
- Material Characterization
- Elemental Impurities
- Compendial Testing
- Impurity Identification
- Nitrosamine Studies
- Extractables and Leachables Testing
- Reference Standard Management and Qualifications
- Environmental Monitoring
- In-Use Studies

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.

Reference Standards Management

Using reference standards or materials — substances used as the standard in an assay, identification, or purity test — allows you to assess the impact of any changes to the manufacturing process. One of the primary challenges in reference standards management is ensuring their authenticity and traceability, requiring extensive documentation and testing. In addition to meeting regulatory requirements, which can be time-consuming and expensive, they must also be handled and stored appropriately to ensure stability and integrity.

Our reference standards management program uses a laboratory information management system (LIMS) to create an efficient process for characterizing all reference standards relevant to each manufacturing process. A certificate of analysis (COA) is delivered to our clients with all our qualified reference standards, including detailed reports from the experiments to support regulatory filings. With analytical teams just a few doors down from our process chemists, our facilities are designed to minimize delays caused by the physical separation of different teams. You can rely on our experts' decades of experience and deep knowledge of regulatory guidelines to deliver high-quality, qualified reference standards.

Stability Testing & Storage

Cambrex, enhanced by Q1 Scientific's world-class stability storage and sample management capabilities, provides a variety of pharmaceutical storage conditions, with walk-in and reach-in chambers that meet all ICH Q1A requirements. Plus, our experts have extensive experience conducting stability studies across the entire life cycle of a product, from early development of the API to process validation of the drug product.

We provide the following standard ICH stability storage conditions:

- 25°C ± 2°C / 60%RH ± 5%RH
- 25°C ± 2°C / 40%RH ± 5%RH
- 30°C ± 2°C / 65%RH ± 5%RH
- 40°C ± 2°C / 75%RH ± 5%RH
- 40°C ± 2°C / 25%RH ± 5%RH
- 60°C ± 2°C
- 5°C ± 3°C
- -20°C ± 5°C
- -70°C ± 15°C
- Custom conditions/validation also available

Microbiology

Cambrex's experienced analysts are well-equipped to ensure microbial safety testing is of the highest quality for our customers and delivered with a quick and reliable turnaround, including:

- Biological indicator testing
- Heterotrophic plate count testing
- Disinfectant qualification
- Filter integrity testing
- Microbial identification
- Antimicrobial effectiveness testing
- Sterilization validations
- Bioburden testing
- Sterility testing
- Bacterial endotoxins testing
- Mycoplasma testing
- Container closure integrity testing

All microbiological testing labs are FDA-registered and fully compliant with all GMP and GLP testing services and standards.

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, 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.