

CAMBREX

INNOVATION



EXPERIENCE



PERFORMANCE





Speed your products to market and improve existing drug products with Cambrex's combination of API development, manufacturing expertise and experience with over 120 APIs, proprietary processes and drug delivery technologies.

CUSTOM DEVELOPMENT AND MANUFACTURING

To speed your products to market, our experienced team will optimize your program to deliver your project on time, within budget and meeting agreed upon quality specifications. We possess the flexibility and the resources to offer a full spectrum of services that are designed to meet your needs.

- Contract research, development and process optimization
- cGMP manufacturing (clinical and commercial scales)
- Dedicated project management
- Six Sigma optimized manufacturing processes for enhanced productivity, quality, safety and project management

GENERIC AND BRANDED APIs AND INTERMEDIATES

Cambrex is a leading global supplier of generic and branded APIs and intermediates to the pharmaceutical industry. Our expertise with European and US intellectual property rights provides our clients with confidence that our proprietary processes are carefully checked to avoid patent infringement. We have expertise in the development, process optimization, scale-up and cGMP production of more than 120 generic and branded APIs and intermediates.

- Synthesis route selection
- Process validation - small scale (1 kg) to large scale (1500 kg)
- Preparation of technical documentation (Drug Master File and IP filings)
- Optimization of existing processes

HIGH POTENCY AND CONTROLLED SUBSTANCES

We provide assurance and peace of mind when manufacturing high potency and controlled substance APIs for our customers. Our production facilities routinely ship grams to metric tons of DEA Schedule II - V controlled substances throughout the world. Each site possesses the required licenses and has the necessary security, inventory controls and facilities in place to meet all regulatory requirements for the development, production and storage of controlled substances and high potency compounds.

- Manufactured and controlled as required by the FDA, DEA, EMEA and other regulatory agencies
- Appropriate for use in research, manufacture and distribution for a wide variety of DEA Schedule II-V products
- Thorough screening and assignment of proper Occupational Exposure Limits to previously uncategorized APIs and intermediates
- Experience with polymer conjugation for various oncology drug delivery therapies
- Facilities and resources to generate toxicology lot to commercial quantities in a cGMP environment

HIGH ENERGY

With many years of experience, Cambrex specializes in highly energetic chemistry production in cGMP facilities. Chemical compounds with a decomposition of more than 1500 J/g are considered high energy, while chemical reactions giving an adiabatic temperature rise of more than 200 °C are considered high energy reactions. Using state-of-the-art facilities, equipment and safety management techniques, Cambrex is a trusted and experienced partner for the manufacture of thermally unstable products and processes.

- Remote controlled cGMP facility for high energy API production
- Process safety management team provides a comprehensive review during route synthesis steps
- Process safety testing laboratory delivers real-time data on hazard potentials
- Rigorous testing provides data to ensure safe handling, storage conditions and transportation

BIOTRANSFORMATIONS

For over 10 years, we have been a market leader in using biocatalysis to create highly pure regio-, chemo- and enantioselective chiral amines and alcohols. Our biotransformation manufacturing processes are efficient and environmentally friendly. We provide custom biocatalytic process development and screening services to meet your needs.

- Highly optically pure products
- Screening services and custom development
- Cost-effective processes
- Eco-friendly production methods
- Research to commercial volumes available

DRUG DELIVERY TECHNOLOGY

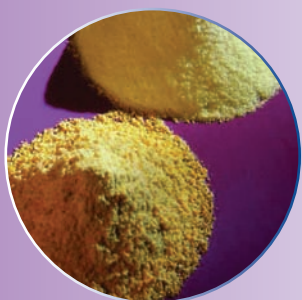
Our proprietary Camouflage™ drug delivery technology is the perfect vehicle for your API. Tasteless, colorless, sugarless and capable of modifying drug release, all products in our API technology enhancement program undergo a series of analytical tests to demonstrate superior drug performance from batch to batch. The Camouflage™ drug delivery platform is compatible with a wide variety of APIs and has exhibited stability enhancement of drug products in a variety of oral dose formulations.

- Flexible formulation options: aqueous suspensions, dry powders for capsules and sachets, orally disintegrating tablets and thin films
- Improved drug stabilization
- Enhanced drug release control



INNOVATION • EXPERIENCE • PERFORMANCE

Products, Services and Technologies



INNOVATION
EXPERIENCE
PERFORMANCE

PRODUCT OFFERINGS

- Generic APIs and intermediates
- Branded APIs and intermediates
- Controlled substances (Schedule II – V)
- Sample product offerings:
 - Fentanyl base and citrate
 - Polyfunctional amines
 - 5-ASA (mesalamine)
 - Methylbenzylamines
 - Amphetamine and amphetamine salts
 - Phenylbutylamines
 - Phenylpropylamines
 - Sulfasalazine
 - Aminotetralins
 - Chiral alcohols
 - Nicotine polacrilex resin
 - Taste-masked APIs
 - Deoxy-branched nucleosides
 - Lactones
 - cGMP polymers
 - Benzoyl peroxide

SERVICE OFFERINGS

- Route selection, development and optimization
- cGMP kilo-lab, pilot plant and commercial manufacturing
- Process and analytical development, qualification and validation
- High Potency API development
- High energy chemistry development
- Safety and toxicology assessments
- Regulatory support
- Stability studies

TECHNOLOGY OFFERINGS

- Biotransformation platforms, custom development and screening services
- Large scale Continuous Flow Microwave Assisted Organic Synthesis (CF-MAOS)
- Camouflage™ drug delivery technology
- Technology-enhanced APIs



CUSTOM DEVELOPMENT

Speed to market, quality, cost of goods and regulatory expertise are critical to commercial viability. An investment in chemical process development can save significant time and money in your cGMP manufacturing campaign and with regulatory authorities as your product moves through clinical development.

Cambrex offers:

- Route selection to obtain a streamlined process from available materials to maximize process efficiency
- Process development to optimize synthetic routes, yields and efficiencies resulting in lower cost of goods
- Analytical development to support your drug application and prepare the CMC submission package for INDs, NDAs and ANDAs
- Process safety assessment for the identification of potential manufacturing hazards at lab, pilot and commercial scale
- Detailed written proposal and sourcing evaluation

Custom Development Capabilities:

- Route selection
 - Literature/database/patent searches
 - Go/No-go feasibility evaluations of key reaction steps
 - 1-10 gram proof-of-concept lots
 - Toxicology lots for animal studies that can be scaled up with confidence
- Time, quality and cost are balanced
- Clinical drug substance supply

Analytical Development Capabilities:

- Method development
- Stability indicating assay methods
- In-process testing methods
- Raw material testing
- Stability testing
- Method qualification



cGMP MANUFACTURING

Cambrex has an uncompromising commitment to cGMP standards, a proven track record of compliance with environmental, health and safety regulations and facilities that are approved to manufacture commercial APIs. We have prepared numerous CMC sections for clients' IND, NDA and ANDA filings.

Process Validation Capabilities:

- Establishing validation protocols
- Analytical method development
- Range finding for critical process parameters
- Optimization/design of experiments
- Laboratory reproducibility studies
- Scale-up and technology transfer
- Validation summary reports
- Active change control system to ensure continued validated operation

Analytical Validation Capabilities:

- Stability indicating and focused degradation studies
- Impurity and limit tests
- Impurity isolation and identification
- Method validation transfers
- cGMP compliance consistent with stage of development
- Strong regulatory track record in supporting regulatory submissions
- Qualified instrumentation

Quality Assurance and Quality Control

Cambrex has an unwavering adherence to quality. We welcome our clients to audit the rigorous quality systems that are critical to our successful inspections by the FDA, EMEA and other world-wide regulatory agencies. Quality is a cross functional effort between our Validation, Document Control, Quality Assurance, Quality Control, Manufacturing, Engineering and Development teams.

Regulatory Compliance

Cambrex is committed to regulatory compliance and has a long history of regulatory excellence. Our manufacturing sites are cGMP compliant and routinely audited by the FDA, EMEA, other governmental agencies and our clients. Our quality and regulatory affairs specialists are actively involved in maintaining conformance to good manufacturing requirements and provide support for clients' IND, NDA and ANDA submissions.

From the importation of raw materials to the manufacture and distribution of APIs, we continue to maintain our excellent compliance record and commitment to quality, making us a trusted and ideal partner for your API manufacturing needs.

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