

Controlled substances

Cambrex is an innovative life sciences company with a refreshingly human approach. Driven by passion, our pharmaceutical products, expertise and technologies are accelerating small molecule therapeutics into the market to help businesses grow.

We offer our customers a truly end-to-end partnership for the research, development and manufacture of their small molecule APIs at every stage of the lifecycle.

Development, manufacture and distribution of controlled substances

Cambrex has held US Drug Enforcement Agency (DEA) licenses for process research, development, manufacturing and importation of Schedule II-V controlled substances for >15 years.

We are one of a limited number of US companies authorized by the DEA to import narcotic raw materials at commercial scale and have been successfully manufacturing highly potent opioids since 2005.

- **Routinely manufacture and distribute commercial quantities of Schedule II-V controlled substances throughout the world**
- **Drug Master Files (DMF) for >20 controlled substances**
- **Controlled substances R&D**

Security and safety

- **Security**
 - Highly secure, controlled access to development and production suites
 - Highly secure, controlled access to waste management systems
 - Highly secure, controlled access to raw materials, intermediates and storage facilities
 - Specialized handling procedures for receiving, transferring, packaging and shipping material
- **R&D laboratory controls**
 - Dedicated laboratory equipment
 - Keycard security system
- **Training and safety**
 - Highly regimented safety protocols and PPE requirements
 - Personnel experienced in handling controlled substances and hazardous materials
 - Highly controlled document protocols and procedures
- **High potent controlled substance**
 - Airlock and cascading pressure differentials to prevent cross contamination
 - Barrier isolation technology
 - Separate gowning, misting and de-gowning areas
 - Equipment cleaning validations at extremely low levels (25 ng/sample)



Matt Williams
Manager
Health & Safety, EHS&S