Cambrex

Information sheet
Drug Substance

Controlled substances

Brad Morton
Group Leader, AD

Development, manufacture & distribution of controlled substances

Cambrex holds US Drug Enforcement Agency (DEA) licenses for process research, development, manufacturing and importation of Schedule I to IV controlled substances. 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 I to IV controlled substances throughout the world
- Drug Master Files (DMF) for >20 controlled substances
- Controlled substances R&D

Security & 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 & 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)

About Cambrex

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

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.