Cambrex

Overview
Drug product

Drug product capabilities and expertise

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.

Drug formulations Expertly finished

From pre-formulation registration batches and clinical supply to commercial manufacturing and packaging, Cambrex delivers your complex dosage forms with expertise.

Custom development
Custom manufacturing
Packaging
Solid state science & pre-formulation development
Conventional dosage forms
Specialized dosage forms

Mahdieh Abazari
QC Analyst

Custom development

- **Formulation development**
- **Analytical development & validation**

Cambrex handles complex oral solid dosage forms, topicals and oral liquids with ease including controlled substances, pediatric dosage, and modified release dosage forms.

In fulfilling all aspects of the CMC dosage form section of the NDA, our laboratories, pilot facilities and experts are with you at every stage of the development process. We take products through excipient iterations, pre-formulation and formulation activities, and the manufacture of clinical trial materials to exacting standards. Our integrated analytical services provide the method development and validation support you need for your registration package – flexibly, efficiently and with an excellent EMEA, HPFBI and FDA inspection record.

Custom manufacturing

- **Technology transfer**
- **Manufacturing capabilities**

With specialized teams and full service EMEA, HPFBI, FDA and DEA (CI-CV) approved facilities, Cambrex is equipped for manufacturing excellence to the highest standards of product quality and regulatory compliance.

Both of our drug product facilities have a variety of equipment and a high likelihood of completing the transfer in a train of equipment that is like-for-like of existing SUPAC category or sub category equipment. Should a supply chain need changing to manufacture an existing product, our experts can manage all aspects of the technology transfer process – seamlessly.

Packaging

Cambrex offers final packaging for solid, liquid, and semi-solid, non-sterile and sterile dosage forms – customer-ready or in custom forms. Primary packaging is conducted in enclosed rooms isolated by air pressure differential from secondary packaging operations. Units of sale are serialized per current regulations. From blister packs and child resistant closures, to blister hospital unit dose and physician samples, we specialize in every shape and form.

Solid state science & pre-formulation development

Cambrex offers fully integrated pre-formulation and formulation services so that selection of drug substance form, solubility testing, excipient compatibility, and drug product development all occur seamlessly within the same department. This is a unique integration in the pharmaceutical industry which allows formulators to begin working with the drug substance earlier and therefore can design a formulation more efficiently.

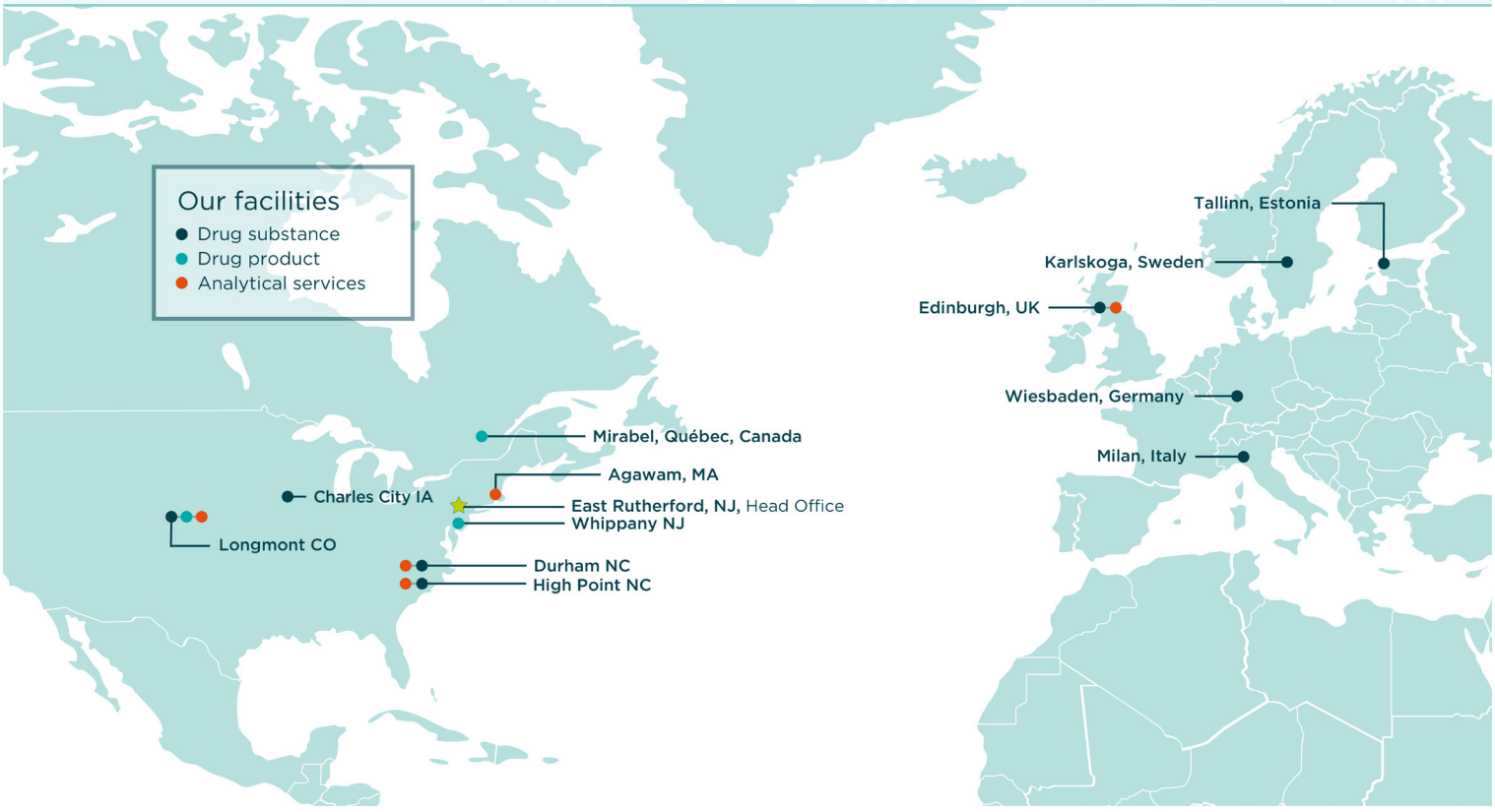
Conventional dosage forms

With fully integrated development and manufacturing services for solid dosage forms, liquids, creams and both sterile and non-sterile ointments, Cambrex experts develop and manufacture drug products with success.

Our development facilities are located alongside our commercial manufacturing set-up, meaning seamless transition from pre-formulation and formulation development through to clinical supplies and commercial supply. All supported by Cambrex's in-house chemistry and microbiology laboratories, robust quality systems and expert technicians to support your manufacturing objectives.

Specialized dosage forms

Cambrex's drug product manufacturing and packaging capabilities cover a wide range of specialized dosage forms, including controlled substances, sterile and non-sterile forms for pediatric and fixed dose combination products. We work closely with you from development through registration, onto the full spectrum of commercial manufacturing services with full compliance and regulatory support provided throughout.



How can Cambrex help you advance? **www.cambrex.com**