CMIC
Pharmaceutical Value Creator

Your Strategic Partner for Expert Drug Development and Manufacturing

Fully Integrated Pharmaceutical Services for Oral Solid Dosage Products

Increasing Our Footprint to Bring New Technologies and Capabilities

CMIC CMO USA has been providing speed and flexibility for drug development and tech transfer needs in the U.S. for more than 15 years. Employing a team of experts with an average tenure of 17+ years, our U.S. location specializes in formulation development and manufacturing for both clinical and commercial oral solid dose products. The state-of-the-art GMP compliant facility with all critical utilities (2 USP Water Systems, Compressed Air, etc. including an emergency back-up generator for critical systems) has strong expertise in fluid bed technology including Wurster, GXR/rotor and granulation processes, as well as compression, encapsulation and functional and non-functional tablet coating operations. The facility also has dedicated R&D suites for product developmental activities, large GLP compliant quality control, analytical R&D laboratories and stability chambers. Our most recent expansion includes contract packaging, including: bottle, blister and pouch/kitting.

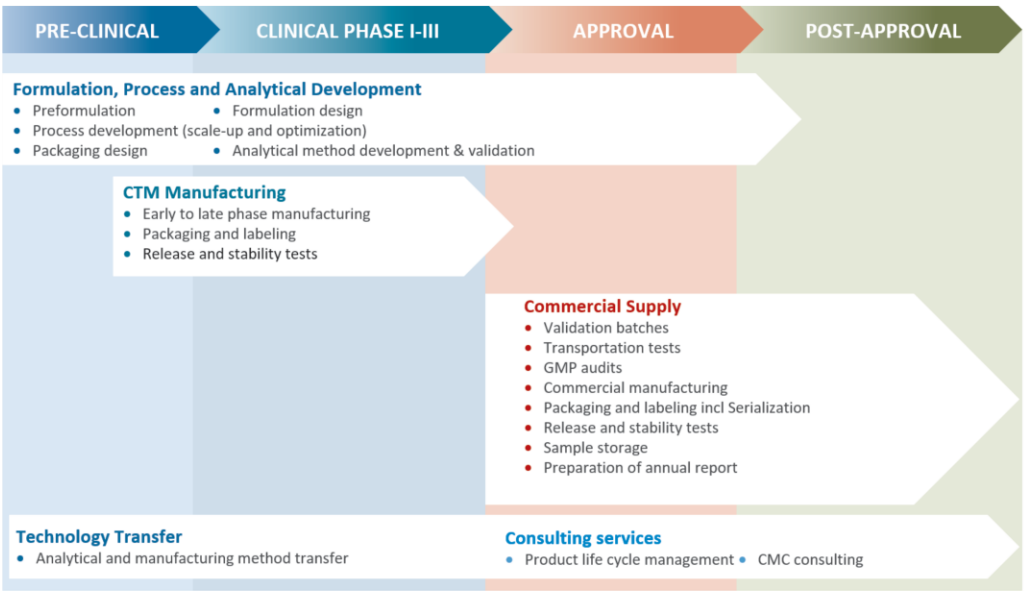
Facility Offerings

CMIC CMO USA's 225,000 sqft facility is located in Central New Jersey, within close proximity to major academic institutions and large multinational pharma companies. The facility is easily accessible to major highways and international airports.

- Expanded GMP manufacturing capacity
- 60 rooms for commercial production and 20 rooms for R&D production with dedicated packaging suites
- Expanded analytical labs, including 4 walk-in stability chambers
- New packaging lines for bottle and blister
- Fully integrated serialization capabilities
- Large refrigerated storage (2-8ºC)
- Large temperature and humidity controlled room for capsule storage

270 Prospect Plains Road
Cranbury, New Jersey 08512

Your Molecule is our Mission



Services and Capabilities

While CMIC CMO USA is accustomed to providing full service to our clients, CMIC can also offer a la carte services based on your specific requirements.

Pharmaceutical Development Services

Our formulation development capabilities are sharply focused on NDA and ANDA oral solid dosage products. Our team will collaborate with you to achieve optimal formulation for your process. We are committed to creating robust processes that provide seamless transition to commercial manufacturing and ultimately to market.

Manufacturing Services

Providing cGMP clinical and commercial manufacturing. Our highly trained staff provides strong expertise in fluid bed technology including, wurster processes and granulation, as well as compression encapsulation and pan coating operations. Our commercial services specialize in solid dosage processes including:

- API and excipient purchasing and release
- Cleaning validation
- Clinical trial materials (CTM) manufacturing
- Registration batch manufacturing
- Process validation
- Commercial manufacturing
- In-process and finished product testing
- Bulk packaging

Analytical Testing & Validation Services

We believe analysis is an essential ingredient for success. CMIC offers a full range of testing services and expertise from development of test methods during the early phases through validation support for product release. We also offer a full spectrum of stability studies.

Analytical Services:

- Analytical method qualification/transfer
- Analytical method development/qualification/verification
- Cleaning verification method development/method validation and testing
- Analytical testing support for development work for selection of optimized formulation
- Raw material and final product testing and release
- Stability studies

Specialized Packaging

CMIC will be adding contract packaging to the list of services provided to our customers in the pharmaceutical, medical device, OTC and dietary supplement markets. With the acquisition of our larger, state-of-the-art New Jersey based facility, we are building dedicated packaging suites with controlled environments as defined by the FDA.

- All packaging suites will be internally regulated for cleanliness
- HEPA filtration systems, meeting temperature and humidity standards for packaging solid oral dosage products
- Packaging capabilities include:
  - Blister packaging capable of producing thermoform and cold form blister units
  - Bottle packaging
- Serialization ready lines

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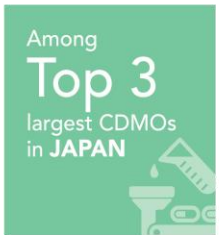

CMIC Group was the first and is the largest CRO in Japan with a global footprint; providing end-to-end services for drug development from preclinical testing, clinical trial management, manufacturing to sales and marketing. As part of the CMIC CMO Group with a global network, our US site is planned for continued expansion of our development, analytical services and commercial manufacturing capacity and capabilities. Our commitment is to provide the essential resources required to meet your present and future needs.

CMIC Group

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