CMIC CMO USA Corporation
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NUMBER OF EMPLOYEES
50

DATE FOUNDED
2007

CORPORATE CAPABILITIES

CMIC CMO USA Corporation

Corporate Description

The CMIC CMO USA Corporation specializes in the pharmaceutical development and commercial manufacturing of NDA and ANDA oral solid dosage products. We provide fully integrated development solutions from early development through high-volume clinical and commercial manufacturing. We are committed to creating robust processes that provide seamless transfer to commercial manufacturing.

Because we believe analysis is an essential ingredient, we offer a full range of testing services, stability studies and expertise from development of test methods during the early phases through validation support for product release.

A highly qualified and skilled staff, with an average tenure of 17+ years, supports our commercial manufacturing. We deliver a strong expertise in fluid bed technology including Wurster processes and granulation, as well as compression, encapsulation, and pan coating operations. Even when working with the most challenging processes, you'll find our people are attentive and responsive to your requirements and deadline commitments.

CMIC development services specialize exclusively on solid dosage processes, which include:

- API and excipient interaction and compatibility
- Formulation and process development
- Expertise with controlled release and sustained release processing
- Dry blending capabilities
- Rotor and high shear granulations and drying
- Fluid bed processes (granulation and drying)

- Wurster bead drug layering and coating
- Tablet compression
- Encapsulation
- Aqueous film coating
- Manufacture drug product for use in clinical trials
- Conduct manufacturing scale up and registration batches
- Provide the technology expertise and validation for commercial manufacturing.

Our analytical services include:

- Analytical methods 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.

CMIC commercial services specialize exclusively on solid dosage processes, which include:

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

All services are offered at our FDA registered site in Cranbury, New Jersey

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