

Your Strategic Partner for Expert Drug Development and Manufacturing



Bridging the West with the East

CMIC Group, the largest and first CRO in Japan, expanded its capabilities into contract development and manufacturing services among its other end-to-end solutions for the pharmaceutical industry. With the acquisition of high standard facilities from global pharmaceutical companies in Japan and specialized dose form technology in the U.S. and South Korea, CMIC Group can provide drug development expertise with advanced manufacturing and packaging platforms to help accelerate your drug development timeline. Whether you are launching new drugs in the U.S. or considering new market entry for the Japanese market, we are your partner for global product development with the ability to seamlessly transfer technologies across borders for manufacturing. With our broad offerings, we can help you tie your development and commercialization needs in the West with the East.

PRE-CLINICAL

CLINICAL PHASE I-III

APPROVAL

POST-APPROVAL

Consulting Services

• Product life cycle management

Regulatory Affairs

• CMC consulting

Formulation, Process and Analytical Development

- Preformulation^{1,2}
- Formulation design^{1,2}
- Process development (scale-up and optimization)^{1,2}
- Packaging design^{1,2}
- Analytical method development & validation^{1,2}

Investigational Product Manufacturing

- Early to late phase manufacturing¹
- · Visual inspections per Japanese requirements
- Packaging and labeling
- Release and stability tests¹
- Labeling for randomization studies

Technology Transfer

Analytical and manufacturing method transfer^{1,2}

CMC Regulatory Services

- CTD preparation^{1,2}
- Regulatory correspondence^{1,2}

Commercial Supply

- Validation batches^{1,2}
- Transportation tests
- GMP audits^{1,2}
- Commercial manufacturing^{1,2}
- Visual inspections per Japanese requirements
- Packaging and labeling
- Release and stability tests^{1,2}
- Sample storage^{1,2}
- Preparation of annual report^{1,2}

All services are provided in Japan

1 Services also provided in the U.S.

2 Services also provided in South Korea

Our CDMO plant capabilities



U.S. New Jersey







Employing a highly qualified staff with an average tenure of 17+ years, our U.S. location specializes in formulation development and clinical trial & commercial manufacturing for oral solid dosage forms. The plant has a strong expertise in fluid bed technology including wurster processes and granulation, as well as compression, encapsulation and pan coating operations.



Japan Shizuoka











Our Shizuoka plant has over 50 years of history providing high quality investigational and commercial product development, manufacturing and packaging of various dosage forms for the pharmaceutical industry. With our dedicated Pharmaceutical Development Center (PDC), scientific expertise and high quality management of manufacturing and packaging for near 100 products annually, we can help you solve your investigational and commercial product development challenges to meet your project timelines.



Japan Toyama







Toyama plant specializes in investigational and commercial manufacturing and packaging of liquid and semi-solid dosage forms, with the capability and safety features for manufacturing products with high-alcohol content.



Japan Ashikaga













Ashikaga plant features state-of-the-art equipment able to manufacture lyophilized vials and sterile solution vial for Highly Potent Active Pharmaceutical Ingredients (HPAPI), biologics and small molecules. The plant also manufactures sterile solution ampoule for biologics and small molecules, and oral dose forms. In addition, the site's unique location protects it from power loss, pulling its power from multiple sources and providing peace of mind.



South Korea Gyeonggi-do



In addition to the manufacturing and packaging of commercial semi-solid products, our plant in South Korea is capable of import and export of medicinal products allowing easy international market access. With its capability of proactive product development, the plant can also offer its own products for out-licensing. With good understanding on product line development, our experienced staff will handle every product as their own to meet your needs.



Contract Research Organization

Experienced non-clinical, clinical and regulatory research & development solutions

Innovative Pharma Model

A flexible service platform providing full pharmaceutical capabilities for overseas business partners to enter Japan

Pharmaceutical Value Creator

A business model of comprehensive services creating added value from preclinical to commercialization

Healthcare Business

Patient and consumer support programs, and clinical site management for hospitals and medical institutions

Contract Development & Manufacturing Organization

Quality solutions for formulation development, analytical testing, manufacturing and packaging

Contract Sales Organization

Broad medical affairs, sales and marketing solutions

CMIC Group

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