

Your Trusted Service Partner for the U.S., Japan, and Asia

Better Medicine Sooner



The First and Largest CRO in Japan Offers You Services Globally

CMIC was founded in 1992 as the first contract research organization (CRO) in Japan. To enable pharmaceutical companies to develop better medicine sooner, we expanded our solutions to include contract development and manufacturing (CDMO), site support, and market solutions, supporting global companies to bring highly desired treatments to the Japanese market.

Leveraging our vast experience and expertise in the medical industry, CMIC also offer solutions using a new ecosystem of healthcare to support individuals and local governments.

We strive to be a **Personal Health Value Creator (PHVC)** to meet our global customers' needs in the U.S., Japan, and broader Asia.

80% of new drug development in JAPAN

Largest
CRO
in JAPAN with
leading
ICCC studies

Top 3
largest CDMOs in JAPAN

The Only CRO in JAPAN with CMC, bioanalysis, and nonclinical services

5,000+ Protocols

70%
of new
ONCOLOGY
drug development
in JAPAN

Completed
400+
oligonucleotide
assays in
the U.S.

15+ Years
of continuous
commercial
manufacturing
and drug
development
services in
the U.S.

Largest regulatory consulting and medical writing team in JAPAN with 140+ Experts

Connected with 3,000+ clinical sites in ASIA-PACIFIC

The First CRO in SOUTH KOREA with experience in 600+ Studies

2nd Largest CSO in JAPAN with over 700+ sales reps, nurses, and MSLs



Our Tailored Solutions

CMIC offers tailored solutions for pharmaceutical companies, medical device manufacturers, academia, bio-ventures, and medical institutions. Using our collective strengths, we offer a broad range of services from pre-clinical research to practical applications.



Japanese Market Entry

Providing full pharmaceutical capabilities for overseas business partners to enter the Japanese market.

- In-country clinical caretaker (ICCC)
- Marketing authorization holder (MAH) services



Asia Clinical Trials

Supporting our clients' clinical trials in 13 countries in the Asia-Pacific region.

- Consulting services
- Regulatory affairs

- Project management
- · Clinical operations



Medical Device & In Vitro Diagnostics

- QMS organization setup
- Design and development
- Nonclinical studies
- Clinical trials

- Approval/certification support
- · Reimbursement support
- Post-marketing surveillance



Oncology Drug Development

Highly specialized oncology experts support your drug development.

- · Consulting services
 - Strategic development planning
 - Study design optimization
- · Regulatory affairs

- · Clinical trials
- · Site and patient support
- CSO services



Orphan Drugs

- · Regulatory affairs
- Manufacturing, packaging/labeling
- · Quality management
- Safety management

- Medical affairs
- Marketing
- · Supply chain management
- Sales and distribution



Regenerative Medicine

Established systems ready to implement and form development strategies and support every stage of the regenerative medicine life cycle.

- Consulting services
- Regulatory affairs

- Nonclinical studies
- · Clinical trials

The Only End-to-End Solution Partner in Japan

Pre-Clinical

Clinical

Consulting

- Drug development consulting
- Japan/foreign market entry
- Medical devices consulting
- Out-licensing to other pharma

Regulatory Affairs

Regulatory submissions and correspondence

Laboratory

- Chemistry manufacturing and control (CMC) and GMP analytical services
- GLP bioanalysis and analytical services
- Nonclinical studies (toxicity, safety, and efficacy)

Formulation Design

• Formulation, process, and analytical development

Clinical Trials

- ICCC/local country agent
- Project management
- Clinical operations
- Data management
- Pharmacovigilance
- Quality assurance and control
- Statistical analysis
- Medical writing
- Patient recruitment and retention

Investigational Product Manufacturing

- Formulation, process, and analytical development
- Early-to-late-phase manufacturing
- Packaging and labeling
- Release and stability tests
- Technology transfer
- Antibody active pharmaceutical ingredients manufacturing

Laboratory

- CMC and GMP analytical services
- GLP bioanalysis and analytical services

Site and Patient Support

- Patient call center and help desk
- Clinical research coordinator (CRC) services
- Clinical site administration support

Medical Affairs

- Evidence generation
- QOL study
- Medical affairs consulting
- Medical science liaison (MSL) talent solutions
- MSL training and assessment
- Patient support program

Other Services and Products

Orphan drugs



CMIC Group can take your product from pre-clinical, to clinical, to commercialization and through post-marketing studies seamlessly.

Whether in the U.S., Japan, or elsewhere in Asia, we are your dedicated, customer-centric, full-service provider across the full drug development continuum.

Filing/Approval

Post-Approval

- · In vitro diagnostics consulting
- CMC Consulting

- · Regenerative medicine consulting
- Product life cycle management

Consulting

- MAH related services
- National health insurance (NHI) pricing
- Health technology assessment (HTA) related consulting

Medical Writing

Commercial Supply

- Commercial manufacturing
- · Packaging and labeling
- Release and stability tests
- Antibody active pharmaceutical ingredients manufacturing

Health Economics and Outcomes Research

Medical Affairs

- Evidence generation
- Medical affairs consulting
- Medical science liaison (MSL) talent solutions
- MSL training and assessment
- Materials review

Patient and Healthcare Services

- Call center
- Patient support program
- Digital healthcare channel service: harmo
- Prescription drug database services
- Healthcare website: HelC
- Self-test services: SelCheck

Post-Marketing Surveillance and Clinical Research

Sales and Marketing

- Sales/medical representative solutions
- Remote detailing services
- Medical device sales support
- Customer service representatives
- Clinical/nurse educator

Agile Access to the World's Major Pharmaceutical Markets

A variety of services can be provided, worldwide, with CMIC facilities or modern technology.



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Pre-Clinical	Consulting	•	•													
	Laboratory	•	•													
	Formulation Design	•	•													
Clinical	Clinical Trials		•	•	•	•	•	•	•	•	•	•	•	•	•	
	Investigational Product Manufacturing	•	•	•												
	Laboratory	•	•													
	Medical Affairs		•													
	Regulatory Affairs		•	•	•	•	•	•	•	•	•	•	•	•	•	
	Site and Patient Support		•													
Filing/Approval	Consulting		•													
Post-Approval	Commercial Supply	•	•	•												
	Medical Affairs		•													
	Patient and Healthcare Services		•													
	Post-Marketing Surveillance and Clinical Research		•	•	•	•	•	•	•	•	•	•	•	•	•	
	Sales and Marketing		•													

^{*}Full range of services for development stage may not be available for some locations.

CMIC's Mission

CMIC is an innovative and unique provider of high-quality solutions for the healthcare industry. We create value by accelerating the access to therapies that improve patients' lives.

CMIC's Vision

To advance the innovation of products and solutions that will empower people worldwide to achieve greater health and wellbeing.

CMIC's Values

W & 3C

WELLBEING: Fully Live Every Moment

Challenge: Liberate opportunity by changing our vantage point

Change: Transform without seeking refuge in conventional wisdom

Communication: Proactively reach out to people and society







Contract Research Organization

Comprehensive support for research and development of disease prevention and treatment

Site Support Solutions

Comprehensive support of medical institutes and medical staff

Personal Health Value Creator

Contract Development & Manufacturing Organization

Development and manufacturing support for pharmaceutical products and biopharmaceutical API from clinical to commercial

Healthcare Revolution

Support individuals, local governments, etc. with solutions using a new ecosystem of healthcare

Market Solutions

Medical, sales and marketing support for pharmaceuticals, and orphan drugs development to commercialization

CMIC Group

Email: information@cmic.co.jp Website: en.cmicgroup.com

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