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

Better Medicine, Sooner

CMIC

Change ourselves. Change the future.

The first and largest CRO in Japan offers you services globally

CMIC stands for **C**urrent **M**edical **I**nformation **C**enter. In 1992, Dr. Kazuo Nakamura founded CMIC as the first Clinical Research Organization (**CRO**) in Japan. He also helped establish the **Japan CRO Association**, laying down the legislative framework needed in order to provide clinical research services for the Japanese pharmaceutical industry.

To enable pharmaceutical companies to develop better medicine sooner, we expanded our solutions to include contract development and manufacturing (**CDMO**), site management (**SMO**), contract sales (**CSO**) and established an innovative pharma model (**IPM**) to bring highly desired treatments to the Japanese market. We strive to be a Pharmaceutical Value Creator (**PVC**), spanning our services across the entire drug development value chain, and meeting our customers' needs in the **U.S.**, **Japan** and broader **Asia**.

We are determined to continue bringing innovation to healthcare to help improve people's lives.

Change ourselves. Change the future.

With our extensive range of services, breadth & depth of expertise, and **proven track record**, CMIC Group is your trusted partner for your drug development success.

Largest CRO in Japan with 1,200+ CRAs

Involved in near 80% of new drug development in Japan

Work with top 10 global pharma companies

Connected with 2,000+ hospitals in Japan

Largest regulatory consulting and medical writing team in Japan with 120+ experts

Experienced in 4,500+ protocols

Among top 5 largest CDMO in Japan

No.1 capacity for stability testing in Japan

2nd largest CSO in Japan with over 550 contract sales reps

Providing speed and flexibility for drug development needs in the U.S.

CMIC Group provides bioanalysis testing and oral solid drug development & manufacturing solutions in the U.S. Based on these services and our broad offering in Japan and Asia, we can help you expand into the U.S. market. We also help new and growing companies meet timelines and scale-up for commercialization utilizing our innovative technology and customer-focused dedication. Let us help you achieve your next milestones faster.

Unique one-stop service partner in Japan

CMIC Group is the only end-to-end solution partner in Japan. If you wish to conduct a clinical study in Japan, we will serve as your required In-Country Clinical Caretaker (**ICCC**). For Japanese market entry, we act as your Marketing Authorization Holder (**MAH**) or connect you with a strategic licensing partner. We will share our expertise as your regulatory consultant to provide solutions for **pharmaceutical products**, **medical devices**, **regenerative medicine** and **in vitro diagnostic products**. As the only Pharmaceutical Value Creator (**PVC**), CMIC Group can take your product from preclinical, to clinical, to commercialization and through post-marketing studies.

PRE-CLINICAL / CLINICAL PHASE I-III

Consultation
- Regulatory affairs
- Method development
- Strategy development

Laboratory
- GLP TK analysis*
- CMC tests
- Quality tests
- Pharmacology and toxicology non-clinical studies (animal & cell)

Study Drug Manufacturing
- Formulation development & stability testing
- Technology transfer & scale-up*
- Clinical trial manufacturing*
- Double-blind packaging

Laboratory
- CMC & GMP analytics
- Bioanalytical (PK, PD, BE) & biomarker services*
- Bioanalytical development, transfer, validation & sample analysis*

Regulatory Affairs
- Strategy development
- Study & protocol design
- ICCC/local country agent
- Regulatory dossier preparation, submission & correspondence
- Medical writing
- Inspection support & interpreter services

Clinical Trials
- Project & vendor management
- Clinical monitoring
- Data management
- Pharmacovigilance
- Medical monitoring
- Quality assurance (audits)
- Statistical analysis
- E-solutions (CTMS, EDC, eTMF etc.)

Clinical Site Management
- Clinical research coordinator (CRC)
- IRB submissions
- Inspections & audit support
- Site contract support

*Services provided in the U.S.

COMMERCIALIZATION / POST-MARKET

Consultation
- Foreign/local market entry, Japan MAH
- Business expansion
- Licensing support
- Regulatory affairs

Pharmaceutical Development
- Formulation, process development & optimization*
- Prototype preparations*

Commercial Product Manufacturing
- Scale-up & quality by design studies*
- GMP manufacturing*
- Packaging

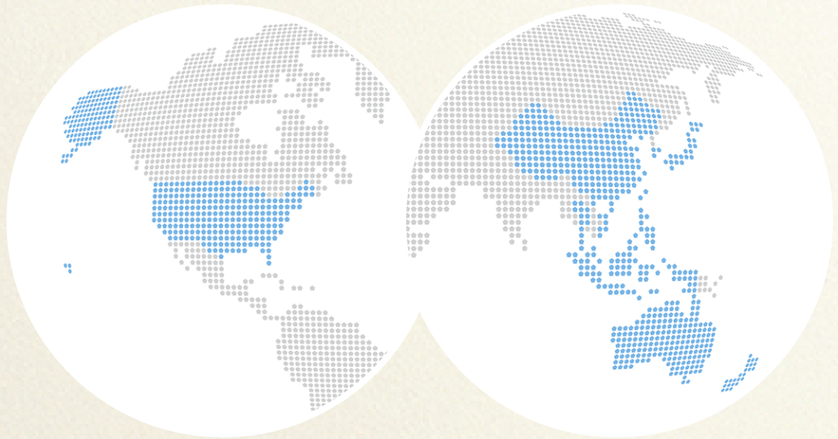
Analytical Services
- Method development and validation*
- Stability & quality tests*
- Release tests*

CSO Solutions
- Contract sales & customer service reps
- Medical affairs consulting and training
- Medical science liaison (MSL)
- Patient & medical institution support programs (web or call center)

Post Marketing Surveillance & Industrial Research
- Risk management plan development & implementation
- Early post-marketing phase vigilance
- Epidemiology studies
- Health economic outcome research & health technology assessment

Agile access to the world's major pharmaceutical markets

CMIC is located where it matters. A variety of services can be provided worldwide with the convenience of modern technology. We also have reliable partners globally, allowing for better medicine, anytime, anywhere.



Services		U.S.	Japan	Korea	Singapore	Taiwan	Malaysia	Hong Kong	Philippines	China	Vietnam	Thailand	Indonesia	Australia	New Zealand
Pre-Clinical	Consultation	✓	✓												
	Laboratory	✓	✓						✓						
Clinical Phase I-III	Study Drug Manufacturing	✓	✓												
	Laboratory	✓	✓						✓						
	Regulatory Affairs		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Clinical Trials		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Clinical Site Management		✓												
Commercialization	Consultation		✓	✓											
	Pharmaceutical Development	✓	✓	✓											
	Commercial Product Manufacturing	✓	✓	✓											
	Analytical Services	✓	✓	✓											
	CSO Solutions		✓												
Post-Market	Post Marketing Surveillance & Industrial Research		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

*Full range of services for development stage may not be available for some locations

We will continue to strive to bring innovation to the field of healthcare.

Our desire to "Provide more effective medicines more quickly" led to our foundation as the first Contract Research Organization (CRO) in Japan in an apartment room back in 1992. Since then, we have developed different types of businesses. And with the support of many customers, we have been able to establish systems that provide services beyond the conventional framework of a CRO, for all types of businesses related to medical products.

In the current environment for medical products and practices, the main focus of new drug development has shifted to diseases with a small patient population, together with the development of technologies for regenerative medicine and biologics. In addition, the entrance of business not traditionally in the healthcare is contributing to the rapid change in our industry. These changes have made customer needs more diverse and sophisticated, generating the need to adapt to globalization and to seek for further efficiencies through the use of ICT.

We will continue to improve the quality of our services as a strategic partner in response to the needs of our customers, and we will also provide our own solutions based on experience and knowledge we have gained from our contract business, and by taking advantage of synergies across businesses. We will address the problems the people are tackling in the field of healthcare one by one, and vigorously support them to devise solutions.

Kazuo Nakamura, Chairman and CEO, CMIC HOLDINGS Co., Ltd.

CMIC's culture: "WELLBEING & 3Cs"

CMIC Group

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