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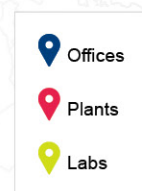
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**Your trustable
Asia-Pacific leading CRO**

Better Medicine, Sooner

Global Deployment



USA

Japan

44

Plants: 4
Labs: 6

Overseas

16

Plants: 2
Labs: 2

History of the CMIC Group

1985 - 1998



2000 - 2006



2007 - 2014



2015 - 2019



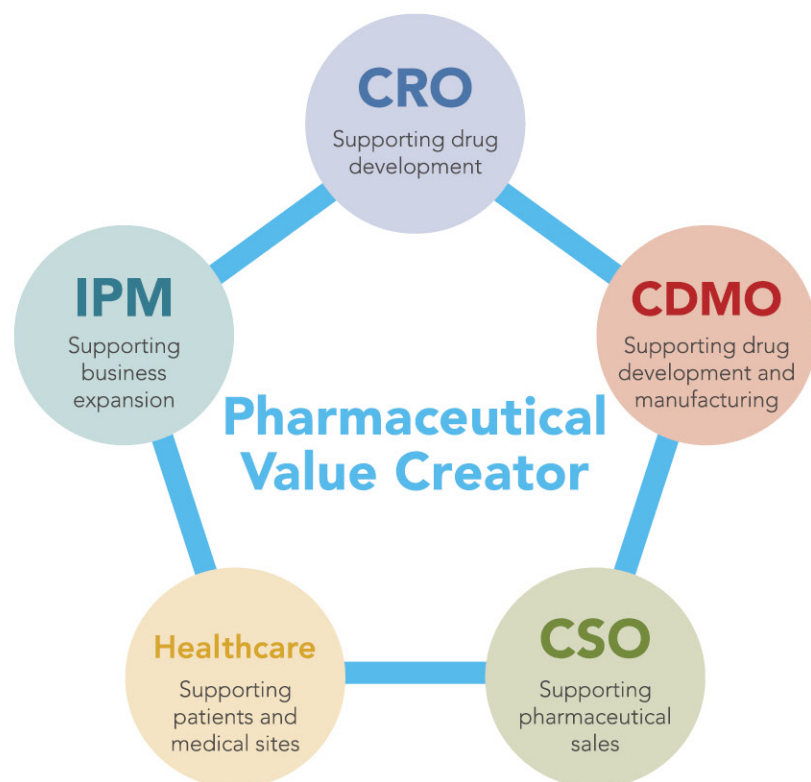
- 1985 Foundation of CMIC Co., Ltd.
- 1992 Commenced full business as the first CRO in Japan
- 1996 Became Japan's first CRO to start Site Management Organization(SMO) service
- 1998 Expansion outside Japan, established the first CRO operation in Korea

- 2000 Commenced Contract Sales Organization (CSO) services through a joint venture in Japan
- 2001 Expanded into China with CRO operation
- 2005 Commenced Contract Development and Manufacturing Organization (CDMO) services
Listing on the First Section of the Tokyo Stock Exchange
- 2006 Established a subsidiary in Singapore

- 2007 Launched CDMO operations in the U.S.A.
- 2012 Converted to a holding company, CMIC Holdings Co., Ltd.
Established OrphanPacific, Inc., a joint venture focusing on orphan drugs and offering Innovative Pharma Model services
- 2013 Established a subsidiary in Malaysia
- 2014 Established a subsidiary in Vietnam

- 2015 Established a subsidiary in Hong Kong
Launched bioanalysis operation in the U.S.A.
- 2017 Established a subsidiary in Philippines
Established a joint venture focusing on analytical research in China
- 2018 Established a subsidiary in Australia
- 2019 Established a subsidiary (CRO services) in Vietnam

Business activities of the CMIC Group: Pharmaceutical Value Creator (PVC) business model



The CMIC Group started business as a company supporting drug development, and it has since developed a broad range of businesses in addition to CRO services, thus developing a unique business model that we call "Pharmaceutical Value Creator(PVC)."



CMIC APAC Services

CMIC CRO Business Unit in Asia-Pacific

Office Operations



Field based Operations

Thailand

Regional Coverage

Indonesia

New Zealand

Non Clinical Services are also available in Japan and US (Chicago)



Supporting your drug development journey with

Strong Asia Presence

PRE-CLINICAL

Consultation

- Regulatory affairs
- Method development
- Strategy development

Laboratory

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

CLINICAL PHASE I-III

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

COMMERCIALIZATION

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*

POST-MARKET

Post Marketing Surveillance & Industrial Research

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

*Services provided in the U.S.

