

• CMIC Holdings Co., Ltd.

Address 1-1-1 Shibaura, Minato-ku, Tokyo, Japan Tel +81 3 6779 8000 (Head Office)

HP www.cmicgroup.com/e

EMAIL infointer@cmic.co.jp (general contact)

● CMIC ASIA-PACIFIC, PTE. LTD.

Address 6 Shenton Way #23-09 OUE Downtown2,

068809, Singapore

Tel +65 6222 2655

◆ CMIC ASIA PACIFIC (MALAYSIA) SDN. BHD.

Address Level 10 Menara LGB, 1 Jalan Wan Kadir, Taman Tun Dr Ismail, 60000 Kuala Lumpur,

Malaysia

◆ CMIC ASIA-PACIFIC (Hong Kong) Limited

Address Room 1302, 13/F., Chevalier House, 45-51 Chatham Road South, Tsimshatsui, Kowloon,

Hong Kong

rel +852 9558 7593

● CMIC ASIA-PACIFIC (AUSTRALIA) PTY LTD

Address L16 71 EAGLE ST BRISBANE CITY QLD

Australia 4000 +61 4 0965 5189

CMIC Korea Co., Ltd.

Address 10F, Gangnam N Tower, 129, Teheran-ro,

Gangnam-gu, Seoul, 06133, Korea

Tel +82 2 3708 3600

● CMIC ASIA-PACIFIC, PTE. LTD.(Taiwan Branch)

Address 5F, No.149, Sec. 3, Xinyi Rd., Da'an Dist.,

Taipei City 10658, Taiwan

Tel +886 2 2706 9947

● CMIC (Beijing) Pharmaceutical Services Co., Ltd.

Address Twin Towers East Building, Unit 1702 B-12 Jianguomenwai Avenue, Chaoyang District,

Beijing, 100022, China

Tel +86 10 6566 5220

◆ CMIC ASIA-PACIFIC (PHILIPPINES), INC.

Address 27th Floor BPI Buendia Centre 372 Sen. Gil Puyat Avenue, Barangay Bel Air Makati City,

1200, Philippines

● CMIC ASIA-PACIFIC (VIETNAM) Co., LTD.

Address Unit S.22, 31st Floor, Saigon Trade Center, 37 Ton Duc Thang Street, Ben Nghe Ward, District 1, Ho Chi Minh City, Vietnam



Better Medicine, Sooner





Global Deployment







Overseas Plants: 2 人 Labs: 2

History of the CMIC Group

1985 - 1998



2000 - 2006



Australia

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)
- 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
- Established a subsidiary in Australia
- 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 is a global CRO, playing a pioneering role in successful global clinical trials in Asia with our access to medical institutions and monitoring tools supported by out rich experience in relevant fields. We are even expanding business area to USA. CMIC supports multinational clinical studies and beyond using a network in the CMIC group. We utilize a wealth of business experience in a broad range of disease specialties, and provide clients with support at all stages of pharmaceutical development, non-clinical studies and from phase I to phase IV clinical studies.

CMIC has 6 core facilities in Japan, US and South Korea, offering total solutions encompassing the entire process of pharmaceutical drug development, from product life cycle and CMC consulting, formulation development, analytical testing, to investigational product and commercial manufacturing.



CSO

CMIC provides Contract Sales services through a joint initiative by CMIC Holdings and UDG Healthcare Group, which includes Europe's largest CSO, Ashfield. The company is 2nd largest in Japan, provides services in three core areas: CSO services with a focus on contracted pharmaceutical sales solutions, medical affairs services including MSL solutions, and contact center leveraging web, telephone, and other remote channels.

CMIC provides Healthcare Business focusing on patient and consumer support programs and clinical site management as a clinical site management organization (SMO) in Japan. Beyond SMO services, we also have drug and medical device call centers with medically qualified persons such as pharmacists, nurses, etc. to support patient and consumers' needs 24/7 for 365 days a year.

Health Care

IPM

CMIC is not only providing traditional fee-for-service support to our customers, but also has a flexible service platform that can provide full pharmaceutical capabilities for overseas business partners to enter into Japan.

Our 50+ experienced consultants will help you determine the best strategy in accordance with Japan-specific changing regulations and unique environment, working flexibly with your company's plans for market entry.

4 CMIC https://www.cmicgroup.com/e/ 5



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*

· Contract sales & customer service reps

CSO Solutions

- · Medical affairs consulting and training
- Medical science liaison (MSL)
- Patient & medical institution support programs (web or call center)

Post Marketing Surveillance & **Industrial Research**

POST-MARKET

- 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.