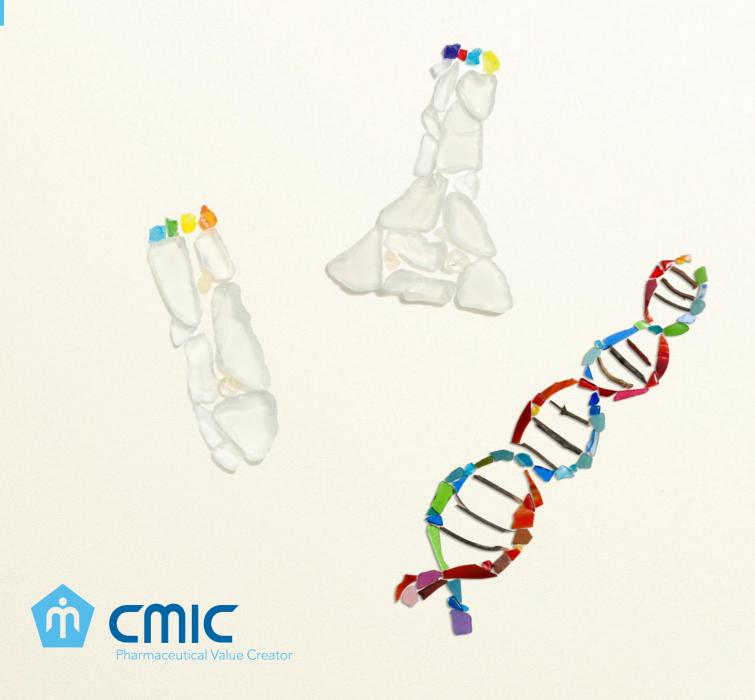
Regenerative Medicine Support Service

CMIC's Regenerative Medicine Solution



End-to-End Solution in Regenerative Medicine/ Cell Therapy Areas

Conditional Marketing Authorization Non-clinical Approval Approval Marketing Basic Development Marketing **Clinical Trial** MAA Manufacture MAA **PMS** Research Commercialization PMS Planning **Marketing Authorization** Marketing Authorization **Regulatory Consulting CTN Support Application Support Application Support** Creation of Document preparation • CTD preparation • NHI pricing support development plan • Response to inquiries Response to inquiries from regulatory authority Data gap analysis from regulatory authority Support of GxP Compliance Inspection Support for obtaining business license, manufacturer license/accreditation

PMDA Consultation

- Document preparation
- Response to inquiries from PMDA

Clinical Trial/Study

- Monitoring
- Project management
- Data management Investigational product management
- Statistical analysis
 Quality assurance
- Pharmacovigilance
 CSR creation

SMO Support for Clinical sites

Patient Recruitment

Post-marketing Clinical Trial Drug Use-Results Survey

Pharmacovigilance

Support for commercial operations/Medical Affairs solutions (CSO)

SMO Support for clinical investigational sites

Call Center

Non-clinical Safety tests

- Toxicity/Efficacy evaluation study Cell proliferation analysis Soft agar colony formation test
- Toxicity/Tumorigenicity test using immunodeficient mouse

Quality assurance tests (GMP)

- Sterility test
- Mycoplasma test
- Analytical testing for control of in-manufacturing process

- Endotoxin test
- Residual test for antibiotics
- Release testing for products

CMC Consulting³

*: Partnership with MEDINET Co., Ltd.



Process development · Contract Manufacturing (CDMO)*

- Manufacture of cellular products for non-clinical study, investigational cellular products and regenerative medical products
- Manufacturing process development

Supply chain service *

- Support for setting specifications
- Preparation of standard operating procedures
- Transportation support for raw materials /product
- Various inspections/ tests

- Cell processing facility management service
- Cell banking

Tailor our services for your needs



Regulatory expertise

CMIC Group set up a regenerative medicine consulting team in May 2015. The team members have years of experience in the regenerative medicine field, including gene therapy, working for pharmaceutical companies and/or academia. With our industry expertise and up-to-date knowledge, we can offer you comprehensive support.



Dedicated Clinical Development team

In October 2016, CMIC formed "Regenerative Medicine of Clinical Research Department" to allocate dedicated resource to support the clinical trials and research.

Experience and Capability >

Cell-based products derived from somatic cells, stem cells or iPS cells (autologous and allogeneic), cancer vaccines (cellular immunotherapy), gene-therapy products and oligonucleotides















GxP compliant facility

We offer raw material testing, in-process control testing, and quality control testing of final products under GMP (GCTP)compliant conditions. In June 2016, we built a new animal research facility that complies with the requirements on safety evaluation of regenerative medicine under GLP.

Partnership with MEDINET Co., Ltd.



Manufacture / Storage / Transportation

By forming a partnership with MEDINET Co., Ltd. who owns the largest domestic cell culture and processing facility (CPF), we have the capability to assist in the development and manufacture of investigational cell products and regenerative medicine products (CDMO).





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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