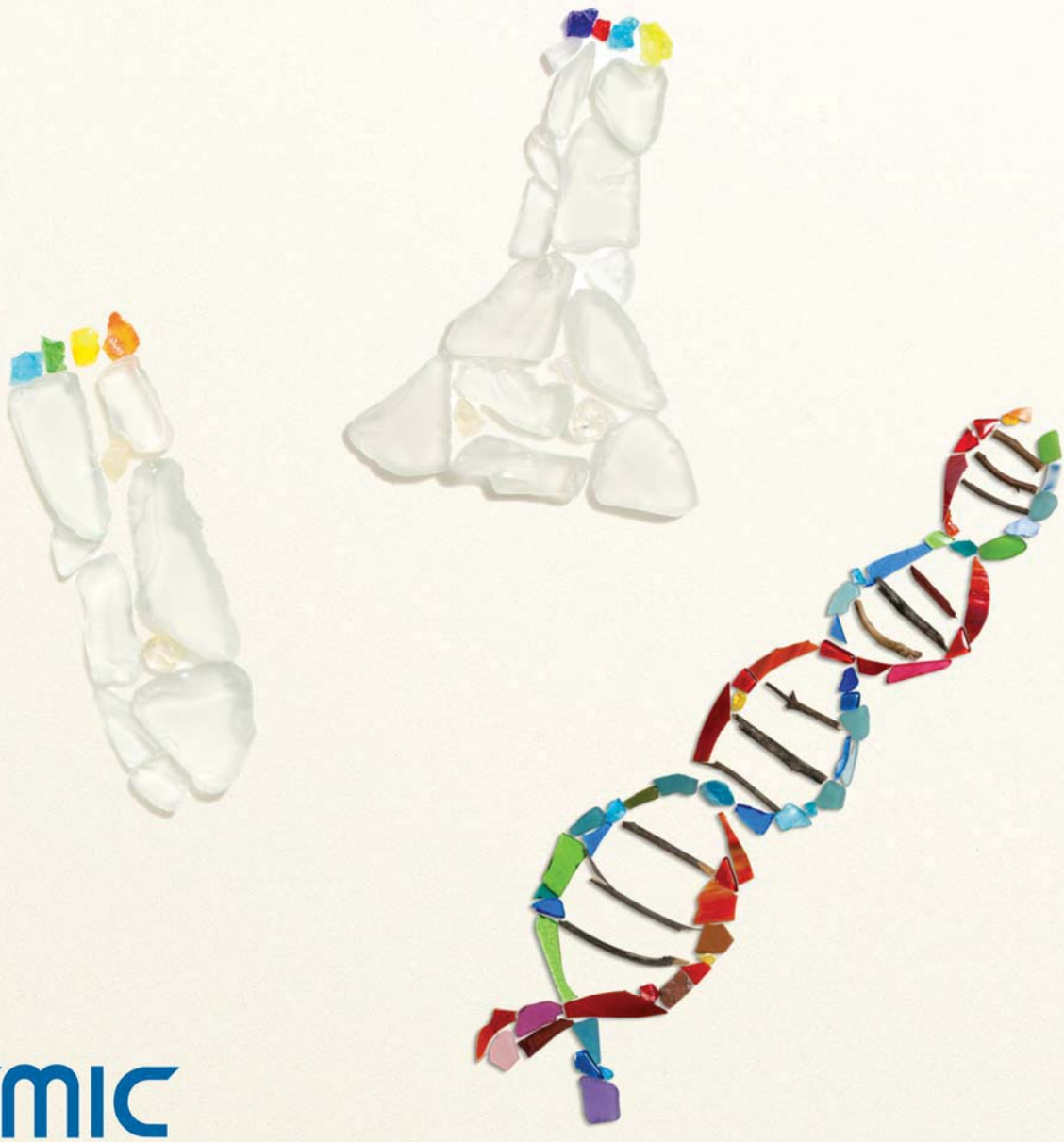
Regenerative Medicine Support Service

CMIC's Regenerative Medicine Solution



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Pharmaceutical Value Creator

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

Basic Research ▶ Non-clinical Development Commercialization Planning ▶ CTN ▶ Clinical Trial ▶ MAA ▶ Approval (Conditional Marketing Authorization) ▶ Manufacture ▶ Marketing PMS ▶ MAA ▶ Approval ▶ Marketing PMS

Regulatory Consulting
- Creation of development plan
- Data gap analysis

CTN Support
- Document preparation
- Response to inquiries from regulatory authority

Marketing Authorization Application Support
- CTD preparation
- NHI pricing support
- Response to inquiries from regulatory authority
- Support of GxP Compliance Inspection
- Support for obtaining business license, manufacturer license/accreditation

Marketing Authorization Application Support

PMDA Consultation
- Document preparation
- Response to inquiries from PMDA

Clinical Trial/ Study
- Monitoring
- Data management
- Statistical analysis
- Pharmacovigilance
- Project management
- Investigational product management
- Quality assurance
- CSR creation

Post-marketing Clinical Trial
Drug Use-Results Survey

Pharmacovigilance

Support for commercial operations/Medical Affairs solutions (CSO)

SMO Support for Clinical sites

SMO Support for clinical investigational sites

Patient Recruitment

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 Consulting*

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

Dispatch of cell processing engineer/researcher*

***：Partnership with MEDINET Co., Ltd.**

Emerging Bio-medical Technology MEDINET

Tailor our services for your needs

Regulatory expertise

CMIC Group set up a regenerative medicine consulting team in May 2015. The team members have average 10+ years of experience in the regenerative medicine field, working for pharmaceutical companies and/or Japanese regulatory authority (PMDA: Pharmaceuticals and Medical Devices Agency). 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).

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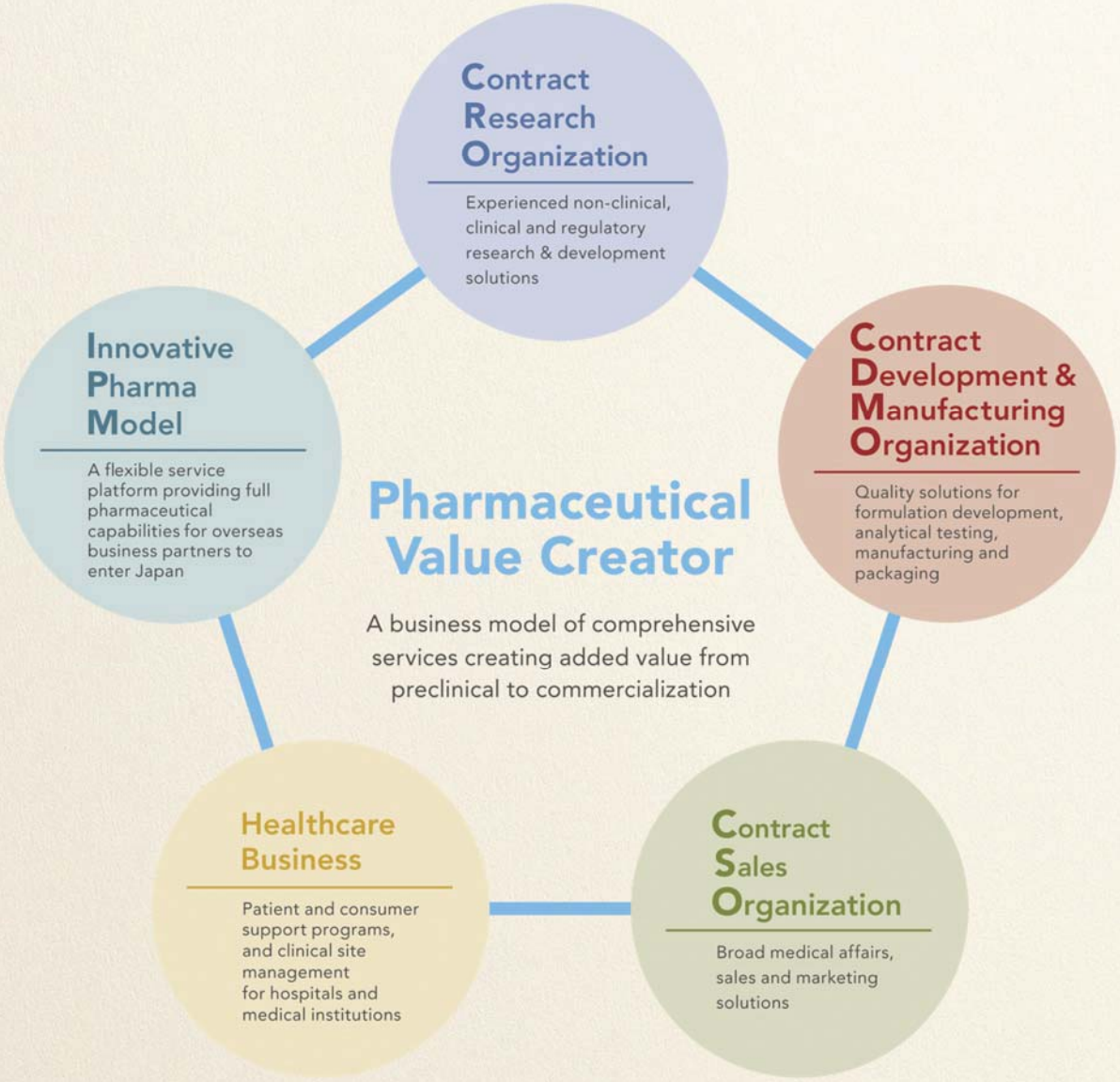

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