CMIC
Pharmaceutical Value Creator

Cell & Gene Therapy Solution

CMIC's End-to-End Solution in Cell & Gene Therapy

Pre-clinical	Clinical	Conditional Approval	Post-Approval	Approval	Post-Approval

Regulatory Consulting
- Development plan
- Data gap analysis

J-NDA Support
- CTD preparation
- Correspondence with regulatory authority
- Marketing Authorization Holder (MAH)
- Price (NHI) consulting
- GxP compliance inspection

J-NDA Support

CTN Support
- Document preparation
- Correspondence with regulatory authority

PMDA Consultation
- Document preparation
- Correspondence with regulatory authority

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

Post-marketing Surveillance

Pharmacovigilance

Cartagena Application
- Document preparation
- Correspondence with regulatory authority

Medical Affairs, Sales & Marketing (CSO)

Clinical Site Support (SMO)

Clinical Site Support (SMO)

Patient Recruitment

Call Center

Patient Communication & Support

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

Quality Assurance Test (GMP)
- Sterility test
- Endotoxin test
- Mycoplasma test
- Residual test for antibiotics
- In-process control test
- Release testing

CMC Consulting *

* Partnership with MEDINET Co., Ltd

Emerging Bio-medical Technology MEDINET

Process Development & Contract Manufacturing (CDMO)*
- Cellular products manufacturing for non-clinical study, clinical trial & commercial supply
- Manufacturing process development

Supply Chain Service *
- Specification Setting
- SOP and document preparation
- Raw materials & products transportation
- Inspections & tests
- Cell processing facility management
- Cell banking

Cell Processing Engineer & Researcher Dispatch*

Tailored Services to Meet Your Needs

Regulatory Expertise

Cell & gene therapy specialized consulting team members have years of experience in the field, working for pharmaceutical companies and/or academia.
With expertise and up-to-date knowledge, we offer you strategic consulting and comprehensive support.

I-IV Dedicated Clinical Development Team

In 2016, CMIC formed "Regenerative Medicine of Clinical Research Department." The experienced team smoothly supports the trials, with optimized operations for each product profile.

Experience & Capability
- Cell-based products derived from somatic cells
- Stem cells or iPS cells (autologous and allogeneic)
- Cancer vaccines (cellular immunotherapy)
- Gene-therapy products
- 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 2016, we built a new animal research facility that complies with the requirements on safety evaluation of cell & gene therapy products 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 (CDMO).

CMIC
Pharmaceutical Value Creator

CMIC グループ
EMAIL: Information@cmic.co.jp WEBSITE: https://en.cmicgroup.com/

Dec 2020