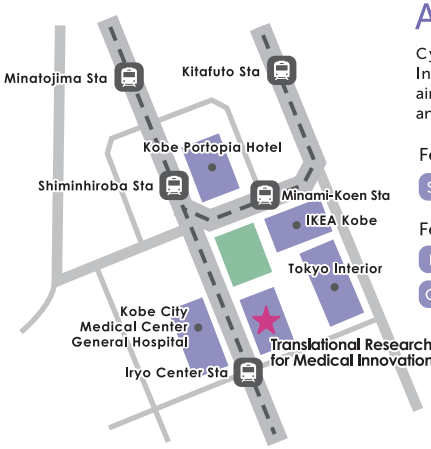
Cyto-Facto Inc.

CMO/CDMO Company Specialized in gene and cell therapy

Cyto-Facto maintain and operate multiple PIC/S GMP-compliant cell processing facilities (CPCs), engaged in contract manufacturing of cell products under facilities and systems that meet international standards. This is the first CMO/CDMO company specializing in gene and cell products in Japan.

Name	Cyto-Facto Inc.
Representative	Shin Kawamata, MD, PhD, CEO
Location	1-5-4 TRI 3F, Minatojima minamimachi, Chuo-ku, Kobe, Japan
Establishment	October 18, 2022
Description of Business	Manufacturing and development of Cell & gene therapy products. Quality control testing
Employees	67 as of July 1, 2023
URL	https://www.cytofacto.com/eng/



Access

Cyto-Facto is located in the Kobe Biomedical Innovation Cluster on Kobe' s Port Island near the airport. Kobe is the capital city of the Hyogo prefecture and the sixth largest city in Japan.

For visitors traveling by train.

Shinkobe Sta ▶ Sannomiya Sta ▶ Iryo Center Sta

For visitors traveling by plane.

Kobe Airport ▶ ▶ Iryo Center Sta

Osaka Airport ▶ Sannomiya Sta ▶ Iryo Center Sta

Cyto-Facto Inc.
Corporate Profile

To improve the health of patients who need cell & gene therapy

Message from the CEO

Linked In

The Foundation for Biomedical Research and Innovation at Kobe (FBRI) was established as a core organization of the Kobe biomedical innovation cluster as a reconstruction project following the Great Hanshin-Awaji Earthquake in 1995.
The Research & Development Center for Cell Therapy (RDC), one of FBRI's organizations, has been researching quality standards for cell preparations used in gene and cell therapy and manufacturing cell formulations commissioned by pharmaceutical manufacturers in Japan and overseas, since April 2023, "Cyto-Facto Inc." has taken over these businesses.

Through the manufacture of commercial products for CAR-T cell therapy, we have accumulated technology,know-how, and knowledge related to manufacturing. Based on these, we are currently proceeding with contract manufacturing of clinical trial products for mesenchymal stem cells (MSC).

There are few companies in Japan that are responsible for CMO/CDMO functions for gene and cell preparations, and the number of companies that have a track record of manufacturing commercial products is extremely limited, but we are proud that the reason why we are selected as a partner is that the following characteristics are recognized.

1. CMO business of Cell & gene therapy products (commercial/commercial) under international GMP standards(PIC/S GMP)

2. process development and investigational product manufacturing business (CDMO business) backed by abundant research knowledge in Cell & gene therapy products.

3. R&D and practical application of new systems for automation and digitization of Cell & gene therapy products manufacturing

Taking advantage of these strengths, we will strive to realize a healthy society by providing the latest gene and cell products to patients who need gene and cell therapy.

Shin Kawamata, MD, PhD
Chief Executive Officer

Cyto-Facto

Our Mission

Cyto-Facto contributes to the health of humankind through the providing cell & gene therapy for patients who need.

ABOUT US

The Foundation for Biomedical Research and Innovation at Kobe (FBRI) was established in 2000 as a core organization to support the cluster of bio-medical companies in Kobe, Japan. The Research & Development Center for Cell Therapy (RDC) was established as the fourth center in FBRI in 2015. The goals of the RDC are to ensure the quality of cell products used in cell & gene therapy to facilitate regulatory approval and to provide cell manufacturing services as a CMO/CDMO for domestic and global biotech and pharma companies.
Beginning in April 2023, Cyto-Facto Inc. will take over the business activities of RDC as an FBRI spin-off company.
Cyto-Facto Inc. will take full responsibility for meeting the demands of society and the healthcare industry for
reliable cell & gene therapy products.

Foundation for Biomedical Research and Innovation at Kobe (FBRI)

- Institute of Biomedical Research and Innovation(IBRI)
- Translational Research Center for Medical Innovation (TRI)
- Center for Cluster Development and Coordination(CDC)
- Research & Development Center for Cell Therapy(RDC) → April 2023

CMO Business

Contract manufacturing of commercial products

Manufacture of commercial cell & gene therapy products at J-GMP AND PIC/S GMP compliant facilities

- Manufacture and shipment of commercial cell & gene therapy products
- Support and consulting for commercial manufacturing
- Technology transfer
- Maintenance and provision of manufacturing SOPs and QC test SOPs
- Preparation of GMP documentation such as deviation and change management
- Construction of various validation SOPs
- Maintenance and documentation of materials, equipment and facilities
- Material acceptance, inventory management
- Manufacturing planning and scheduling of commercial product manufacturing

CDMO Business

Process development of manufacturing of clinical trial products

Process development and manufacturing of clinical trial products related to seeds of cell & gene therapy products of pharmaceutical companies and bio-venture companies

- Manufacturing of cell & gene therapy clinical trial products
- Support and consulting for clinical trial manufacturing
- Consulting including GMP/GCTP gap analysis
- Construction of manufacturing SOPs from experimental protocols for various cell types
- Construction of closed manufacturing system, introduction of automatic culture equipment
- Consulting for the introduction of integrated electronic systems
- Construction and maintenance of manufacturing SOP and QC test SOP

Quality control testing of cell & gene therapy products for commercial, clinical and research use

Quality control tests in accordance with the US, EU and Japanese Pharmacopoeia and relevant GLP testing procedures as defined by regulatory agencies.

- In-process inspections and shipping inspections
- Mycoplasma Testing (NAT)
- Endotoxin test
- Testing using FCM (cell surface antigen analysis, etc.)
- Product-specific quality control tests (differentiation experiments, CTL analysis, etc.)
- Preparation and submission of quality inspection reports

Provision of integrated manufacturing management systems

Provision of "CytoFactory 4.0", an integrated manufacturing management system that promotes efficient production of cell and gene products

- Development of an IT-based integrated manufacturing management system for information on manufacturing processes in existing cell formulations and automated manufacturing systems
- Sell to pharmaceutical companies, CMOs, etc., and build a support system and collaborate.
- Promote the integration of information by introducing IoT manufacturing and QC information and collecting information including supply chains.

Consultation for regulatory issues

Comprehensive consultation service for issues regarding process development, the manufacturing process, and relevant regulatory issues so as to facilitate clinical trials and the obtaining of market approval.

- Practical consulting for the manufacture of clinical trial or commercial products related to the client's cell & gene therapy seeds
- Consulting for the development of automatic culture equipment and integrated manufacturing systems
- Gap analysis under PICS/GMP and J-GMP management
- Training of manufacturing, quality control and quality assurance members for clinical trials and commercial manufacturing
- Practical consulting by experts (Ph.D. and master's degree holders) based on their experience in manufacturing commercial products for cell & gene therapy preparations (manufacturing, quality control, quality assurance)