

Kobe Regenerative Medicine Study Group

Member Company Introduction

2025



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List of FY 2025 Member Companies *in 50 Japanese syllabary order

Regular Member

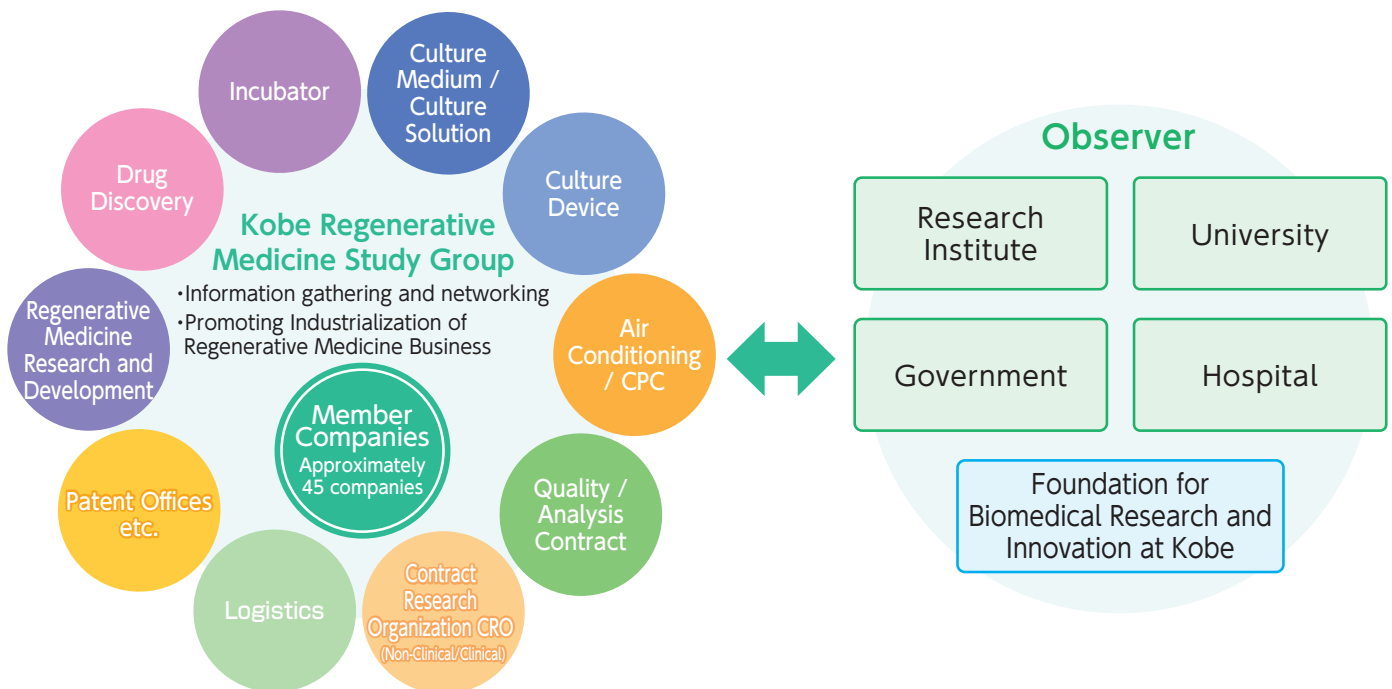
1 IQVIA Services Japan G.K.	25 Toray Research Center, Inc.
2 Iwatani Corporation	26 TOPPAN Inc.
3 Air Water Aeras Bio Inc.	27 NARD Institute, Ltd.
4 OKURA INDUSTRIAL CO., LTD.	28 Nissin Corporation
5 Otsuka Pharmaceutical Co., Ltd.	29 Japan Blood Products Organization
6 Oriental BioService, Inc.	30 NextGeM Inc.
7 Oncolys BioPharma Inc.	31 Vision Care Group (VCCT Inc./Vision Care Inc./VCGT Inc.)
8 KANEKA CORPORATION	32 Hitachi, Ltd.
9 Cyto-Facto Inc.	33 PHICELL Corporation
10 ZACROS Corporation	34 FUJIFILM Corporation
11 SANKEN SETSUBI KOGYO CO., LTD.	35 Bourbon Corporation
12 JCR Pharmaceuticals Co., Ltd.	36 VectorBuilder Japan, Inc.
13 SYSMEX CORPORATION	37 HEALIOS K.K.
14 SINFONIA TECHNOLOGY CO., LTD.	38 Matrixome Inc.
15 SUZUKEN CO.,LTD.	39 Mizuta Seisakusho Co., Ltd.
16 Sumitomo Rubber Industries, Ltd.	40 MITSUI-SOKO HOLDINGS Co., Ltd.
17 Seiken Co.,Ltd.	41 RACTHERA Co., Ltd.
18 Celaid Therapeutics Inc.	42 Rebirthel Co., Ltd.
19 Daikin Industries, Ltd.	
20 DAI-DAN CO., LTD.	
21 ViSpot Division, Takara Bio Inc.	
22 TMI Associates	
23 Texcell Japan KK	
24 TechnoPro, Inc. TechnoPro R&D, Company	

Supporting Member

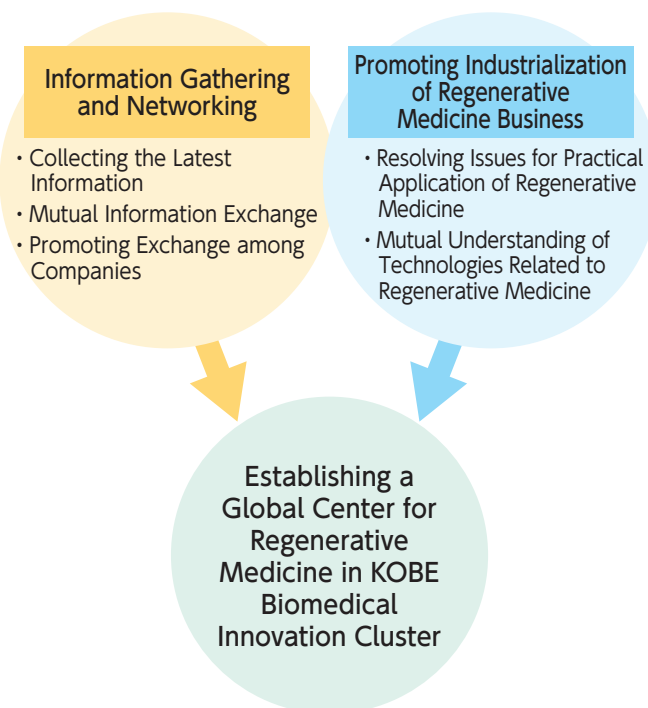
1 Otsuka Pharmaceutical Factory, Inc.
2 CM Plus Corporation
3 Sumika Chemical Analysis Service, Ltd.
4 Mediford Corporation

Introduction to the Kobe Regenerative Medicine Study Group

Global Center for Regenerative Medicine in KOBE Biomedical Innovation Cluster



■ Role of Kobe Regenerative Medicine Study Group



■ Management Structure of Kobe Regenerative Medicine Study Group

Member ※

- ①Regular Member
Regenerative medicine-related companies that have a base in KOBE Biomedical Innovation Cluster, as well as those with their headquarters or main offices located within the Kobe city.
- ②Supporting Member
Regenerative medicine-related companies not falling under category ①, which collaborate to support the activities of the study group.
- (In principle) Up to 6 members can participate
- Annual fee: ①Regular Member 50,000 yen/company
②Supporting Member 100,000 yen/company

※The annual fee will be reduced or waived if the content of the activities changes due to unavoidable reasons.
Companies interested in joining are, in principle, permitted to attend one study session as provisional members.



Observer

- Invite temporary observers as needed
- From research institutes, universities, public offices, hospitals, etc.
Appointed by the secretariat in consideration of the requests, etc.

Management System

Secretariat (planning and management):
Foundation for Biomedical Research and Innovation at Kobe

Content of Activities

- 4 study meetings per year (in principle)
- Structure: Lecture + company presentation + social gathering
- Includes special events, individual consultation, matching, etc.



Past Activities of the Study Group

Activities

FY2023

The First Event : Wednesday, June 15

Tokyo University of Science	Tetsuhito Takarada
Kitasato University	Masato Fujioka
Company Introduction	
xCARE Inc. Hitachi, Ltd.	

The Second Event : Tuesday, October 24

The University of Osaka	Yoshiki Sawa
Axcelead Drug Discovery Partners, Inc.	Hideo Fukui
Company Introduction	
Seiken Co.,Ltd. Celaid Therapeutics Inc. Rebirthel Co., Ltd.	

The Third Event : Thursday, February 22

Pharmaceuticals and Medical Devices Agency	Akiyoshi Kunieda
Pharmaceuticals and Medical Devices Agency	Fumito Mikashima
Pharmaceuticals and Medical Devices Agency	Akira Sakurai
Pharmaceuticals and Medical Devices Agency	Jun Matsumoto
Company Introduction	
Oriental BioService, Inc. VectorBuilder Japan, Inc.	

FY2024

The First Event : Monday, May 27

Shinshu University	Yoza Nakazawa
C4U CORPORATION	Akimitsu Hirai
PtBio Inc.	Keisuke Okuhara
Company Introduction	
Bourbon Corporation TechnoPro, Inc. TechnoPro R&D, Company	

The Second Event : Monday, September 30

Ministry of Health, Labour and Welfare	Kazuki Morita
Pharmaceuticals and Medical Devices Agency	Emiko Hirayama
Novartis Pharma K.K.	Hirohito Katayama
Company Introduction	
FUJIFILM Corporation Toray Research Center, Inc.	

The Third Event : Thursday, March 13

National Institute of Health Sciences	Akiko Ishii
The Jikei University School of Medicine	Saki Matsushima
National Cancer Center	Tetsuya Nakatsura
National Center for Child Health and Development	Masafumi Onodera
Company Introduction	
Allied Laboratories Co., Ltd. JFE Techno-Research Corporation TMI Associates TOPPAN Inc. Kansai Bureau of Economy, Trade and Industry	

Special Event

This event is open to non-members.
Once a year, a hybrid event is held in Tokyo under the name of "Regenerative Medicine Industrialization Forum."

2024: Thursday, January 23, 2025

Meeting Venue:
(Tokyo Venue)Tokyo Midtown Yaesu Conference

*Please check the event details at the following URL

https://www.fbri-kobe.org/news/detail.php?news_id=1362

※Japanese site



Topics on Regenerative Medicine in KOBE Biomedical Innovation Cluster

Oncolys BioPharma Inc.

Aim to submit an application for OBP-301, an oncolytic virus, within 2025. A Prior Consultation under the SAKIGAKE Designation System is currently in progress.

<https://ssl4.eir-parts.net/doc/4588/tdnet/2624275/00.pdf>

※Japanese site



Nissin Corporation

A new warehouse, including refrigerated and frozen storage facilities, is currently under construction in Nish-ku, Kobe. Completion is scheduled for September 2026.

<https://www.nissin-tw.com/english/news/hyogo20250120.html>



Member Company Profiles *in 50 Japanese syllabary order

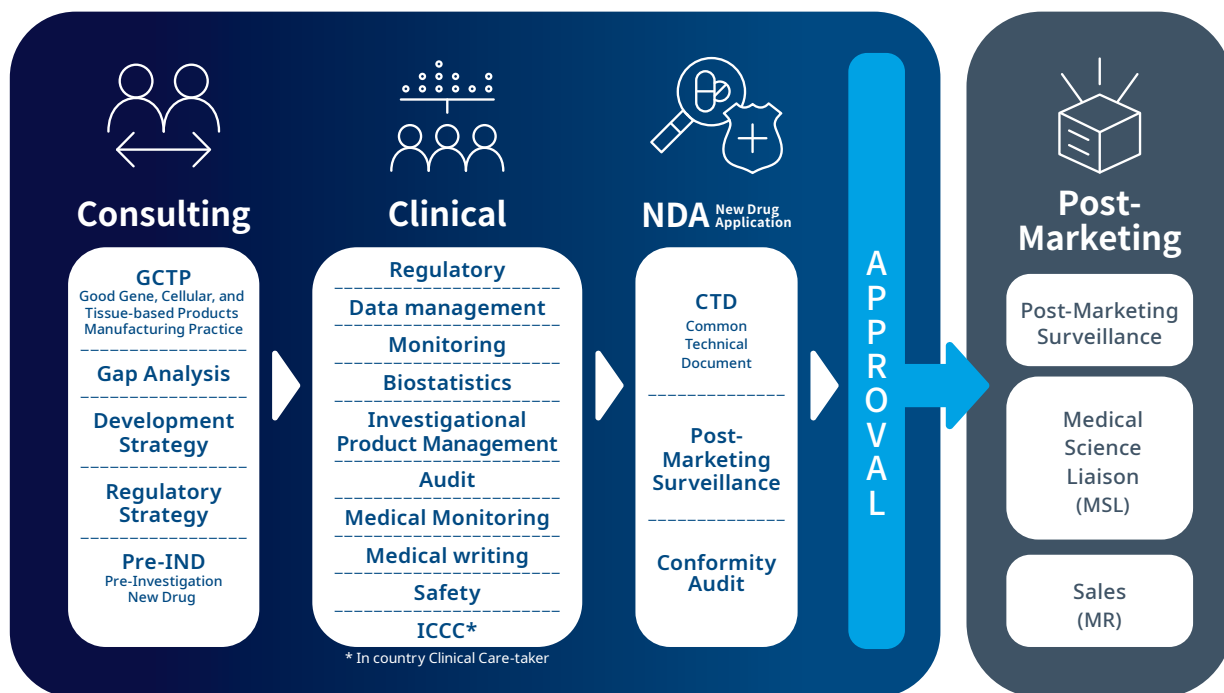
*Click on a company name to view more details.

Company Name	Information Pages	Regenerative Medicine Research and Development	Drug Discovery	Incubator	Culture Medium/ Culture Solution	Culture Device	Air Conditioning/ CPC	Quality/ Analysis Contract	Contract Research Organization (Non-Clinical/ Clinical)	Logistics	Patent Offices, etc.	Others
Regular Member												
IQVIA Services Japan G.K.	5											
Iwatani Corporation	6											
Air Water Aeras Bio Inc.	7											
OKURA INDUSTRIAL CO., LTD.	8											
KANEKA CORPORATION	9											
Cyto-Facto Inc.	10											
ZACROS Corporation	11											
SANKEN SETSUBI KOGYO CO., LTD.	12											
JCR Pharmaceuticals Co., Ltd.	13											
SINFONIA TECHNOLOGY CO., LTD.	14											
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DAI-DAN CO., LTD.	19											
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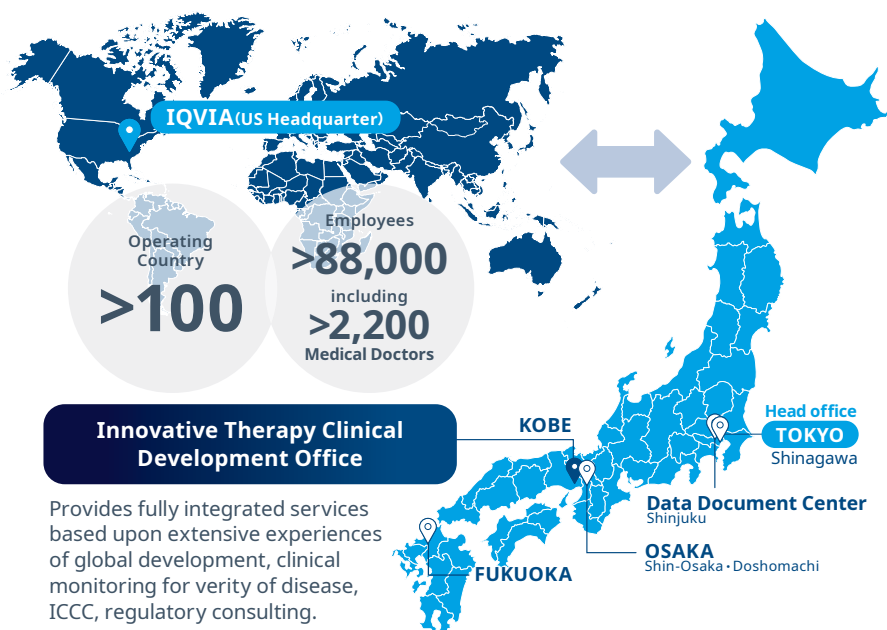
IQVIA Services Japan G.K.

Provide services to support Clinical research / Clinical trial in Human (CRO)

IQVIA implements wide variety of solutions for help regenerative medicine products from research stage to post marketing stage.



IQVIA is a leading global healthcare provider, accelerating innovation for a healthier world



About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. IQVIA Connected Intelligence™ delivers powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients.

CONTACT US

IQVIA Japan Group IQVIA Services Japan G.K

Keikyu Dai-1 Bldg., 4-10-18 Takanawa, Minato-ku, Tokyo
TEL : 03-6859-9500 E-mail : Japan@iqvia.com URL: www.iqvia.co.jp



BIOxGAS



LN₂
LCO₂



LN₂
small tank



CO₂



Dry ice



Cryopreservation
container for cell storage



RFID specimen
Management
system



Shipper for
transport



Temperature
logger



Gas detector



Area
elimination
system



Isolator



Pharmaceutical
equipment



CE tank and
vacuum
insulation
piping



LPG emergency
generator

Regenerative medicine and cold chain also Iwatani

Iwatani

Iwatani Sangyo Kobe branch
Industrial Gas ▪ machinery
department

Sayumi Yamashita
TEL: 078-336-5400
FAX: 078-336-5405



World's First Dental Pulp Regenerative Therapy from Kobe Contributing to the Development of Regenerative Medicine and Dental Health



Bank Storage Service

We store dental pulp stem cells for use in regenerative medicine. They can be used in dental pulp regenerative medicine, which is already in practical use.

Research on Dental Pulp Regenerative Medicine

Pulp regeneration therapy, which was commercialized for the first time in the world in 2020, is attracting attention as a new option to preserve your own teeth.

Utilization of Dental Pulp Stem Cells

We manufacture pulp stem cells for regenerative medicine on contract and provide pulp stem cells for research institutions.

◆ For research institutions:
<https://aerasbio.co.jp/public-information-about-samples/>



Mascot Character
shizuichan

We use friendly characters on SNS, etc.

We convey the importance of dental pulp, the nerve of the tooth, and promote regenerative medicine and dental health.

We look forward to following each other.

Please feel free to contact us via DM on X (formerly Twitter).
our company X: <https://twitter.com/aerasbio>



1 -3 -1 Minatoshima Minami-machi, Chuo-ku,
Kobe-shi ,Hyogo
(8 minutes walk east of Medical Center Station)



TEL:078 -777 -4386 WEB:<https://aerasbio.co.jp/>

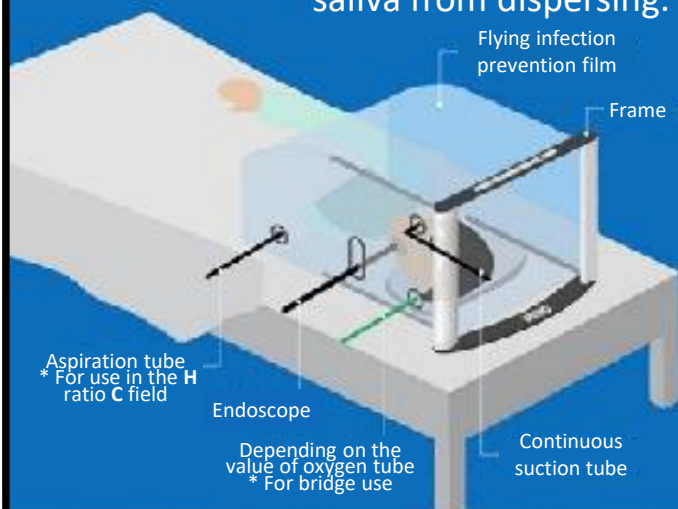
Single-Use Bag for biopharmaceutical processing



- 1 Ingredient does not include any additives
- 2 Processing the bags in a Class 10,000 clean room
- 3 Assembly and other customization available

■ Endo barrier[®] Virus infection prevention system for endoscopes against droplet infection

This is an infection prevention system that allows you to take examinations in a safe environment while preventing droplets and saliva from dispersing.



- 1 **Minimizing droplet spread**
By making the patient side into a box and making the space negative pressure (suction), direct exposure and indoor dispersion can be minimized.
- 2 **Easy operation (foldable)**
It can be set less than one minute and the treatment can be performed as usual. The frame can be folded and stored.
- 3 **Disposable**
The components (Mouthpiece, each tube, etc.) to which the droplet adheres can be disposed. They can be wrapped in a disposable film and discarded. This saves labor in disinfecting the frame.

■ Processing technology

Utilizing our company elemental technologies such as film making, coating, and bonding, which we have cultivated mainly through film manufacturing, we will engage in research and development to create attractive products that meet user requirements.

Contact: OKURA INDUSTRIAL CO., LTD. R&D Center Marketing Department
Address: 1515 Nakatsu-cho, Marugame, Kagawa Prefecture
Phone: 0877-56-1158
Contact: Yoshimura t-yoshimura@okr-ind.co.jp
Yuguchi j-yuguchi@okr-ind.co.jp



OKURA INDUSTRIAL CO., LTD.

Website

<https://www.okr-ind.co.jp/>

Creating materials and products that can contribute to people's health and medical care

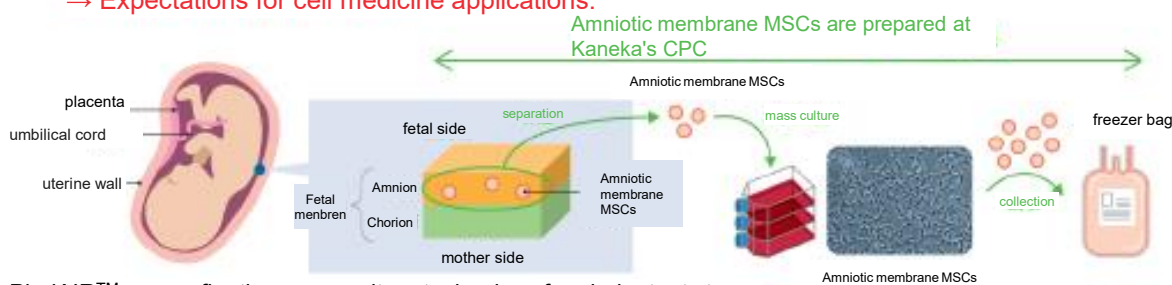
[Product and Technology]
Human Amnion-Derived Mesenchymal Stem Cells

Features of Kaneka Amniotic MSC

- Manufactured using mass culture technology
 - Large quantities of cells from the same donor can be prepared, enabling mass production and stable supply
- CPC for Kaneka Amniotic MSC production has obtained a specific cell processing license and is compliant with GCTP
 - Can be developed for clinical application and can be used for commercial use in the future

Features of amniotic membrane and amniotic MSC

- Amniotic membrane is procured from domestic medical institutions.
→ Can be used as a cell source for domestically produced cell preparations.
- Animal experiments have confirmed that amniotic membrane MSCs are hypoinmunogenic and have immunosuppressive and tissue repair effects.
→ Expectations for cell medicine applications.

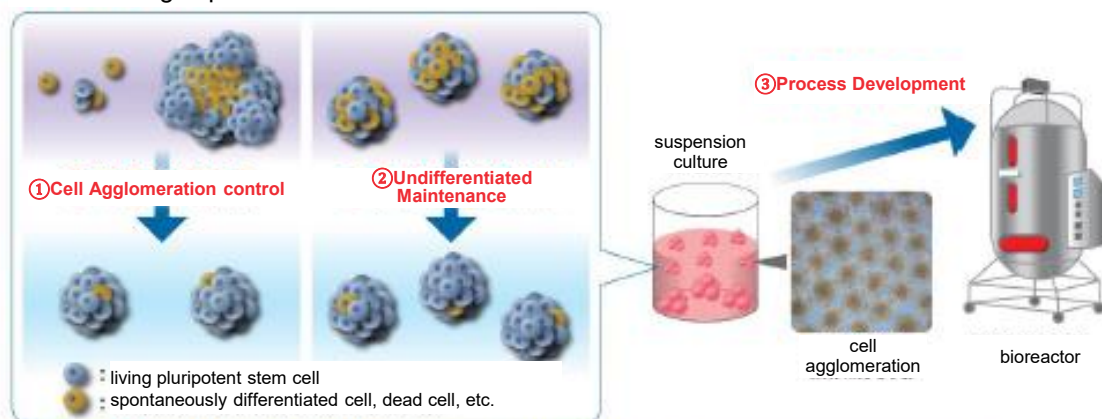


PluriAIR™, a new floating mass culture technology for pluripotent stem cells

Technology Overview

A novel suspension culture technology for pluripotent stem cells(iPS/ES cells) (Patent No.6238265)

- ① **Cell Agglomeration control** : Technology for adjusting the size of cell aggregates
- ② **Undifferentiated Maintenance** : Technology to suppress spontaneous differentiation
- ③ **Process Development** : Developing a manufacturing process using bioreactors with GMP manufacturing experience



Contact: Kaneka Institute for Regenerative Medicine, Inc. Tomoyuki Nakaishi
Kobe MI R & D Center 3 F, 6 -7 -3 Minatojiminami-machi, Chuo-ku, Kobe, 650
0047

TEL: 050-3133-7903 Mail: Tomoyuki.Nakaishi@kaneka.co.jp^[LINK1]

General website for regenerative medicine:

<https://www.kaneka.co.jp/saiseisaibo/index.html>



**Cyto-Facto is a CDMO specializing in gene and cell products.
We provide one-stop, high-quality services from initial
development to commercial product manufacturing.**



Services

Process development, clinical trial product manufacturing, commercial product manufacturing (CMO/CDMO)

Operating multiple PICS GMP-compliant cell manufacturing facilities
Providing global standards based on our experience in commercial production of CAR-T products

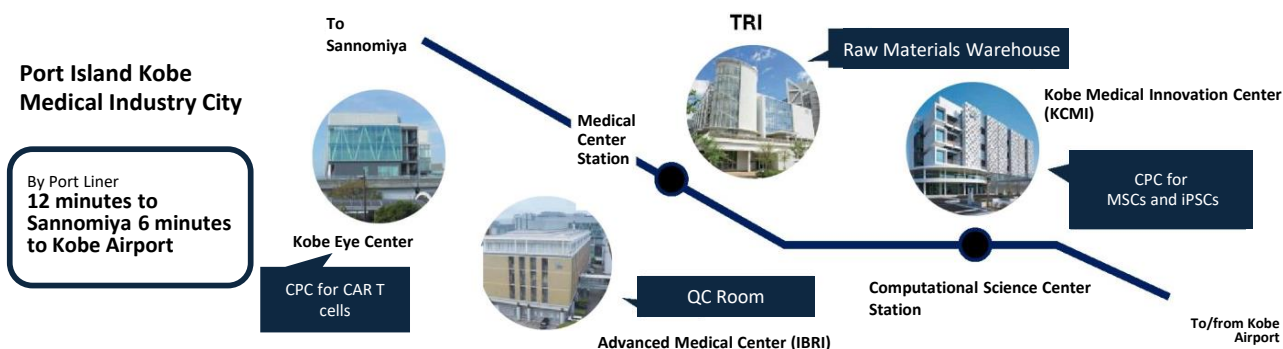
Consigned quality testing and characterization

Quality control tests, analytical validation, and the launch of test systems in compliance with the Japanese Pharmacopoeia and GCTP/GMP

Development, sales, and services of integrated manufacturing management systems

Support for digitalization of manufacturing sites through the provision of CytoFactory 4.0, a cloud-based integrated manufacturing management system

Our Manufacturing Sites



Contract manufacturing and quality testing of gene and cell products

Please feel free to contact us first.

www.cytofacto.com/contact/

info@cytofacto.com



Cyto-Facto Inc.

3rd Floor, Shimin byoin mae Bldg.,
-1-11 Minatojima-minami-cho 2, Chuo-ku, Kobe, Hyogo 650 0047, Japan
www.cytofacto.com

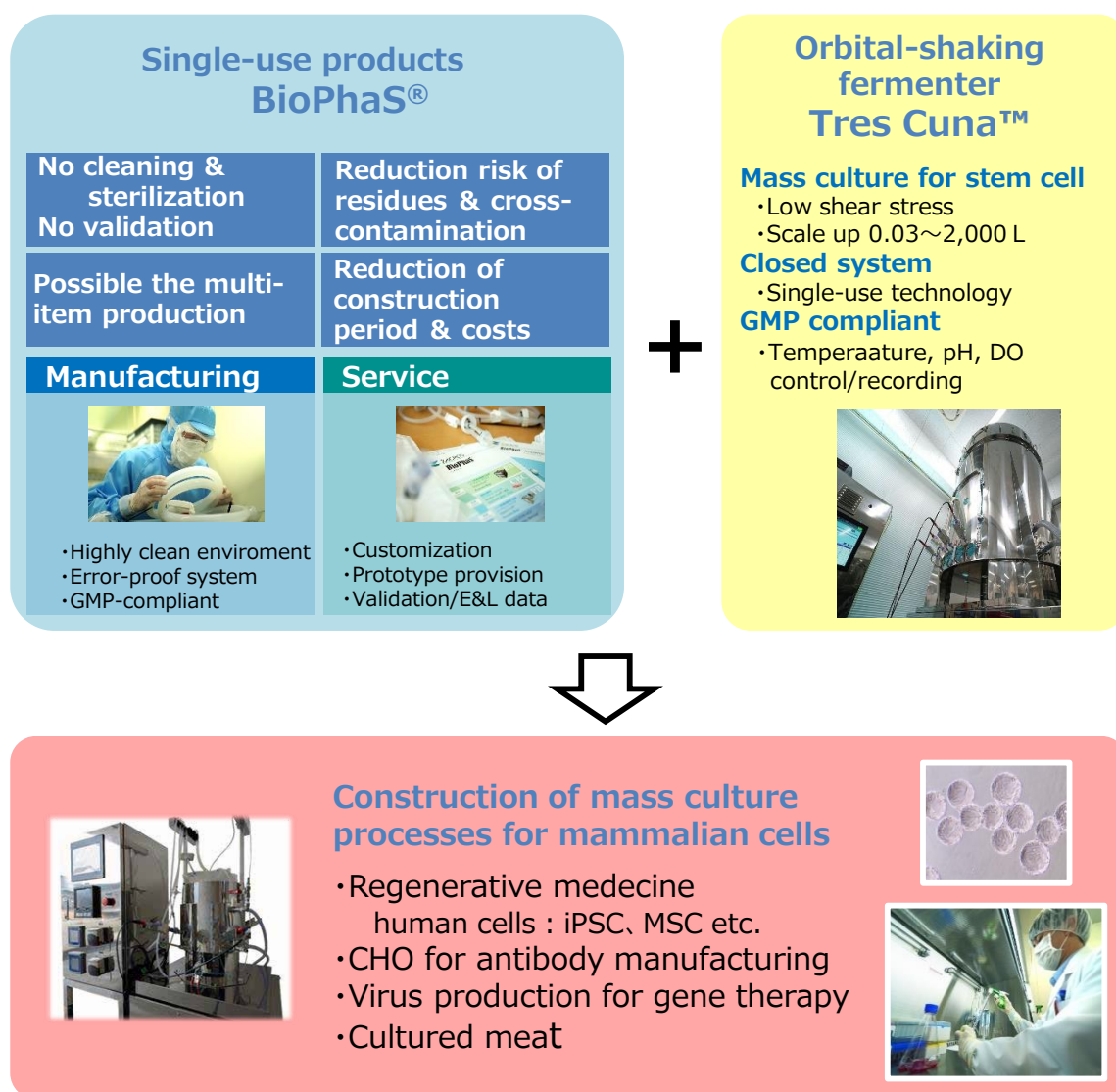


ZACROS

ZACROS Corporation

BioPhaS[®]

Single-use products for manufacturing of
Biopharmaceuticals and Regenerative medicine.
--R&D to manufacturing--



**Contribute industrialization of regenerative medicine,
as a domestic manufacturer of single-use products**

6-3-5, Minatojima minami-machi, Chuou-ku, Kobe
TEL:078-302-3307

Reliable Technical Expertise for CPC Facility Development

One-Stop Solutions: From Planning to Maintenance

Sanken Setsubi Kogyo applies advanced technical expertise, built on extensive experience and a proven track record, to meet the specialized demands of regenerative medicine and cell processing facilities. We offer detailed, end-to-end services across the entire facility lifecycle. These include GMP and GCTP-compliant planning and design, operations-aligned maintenance, and facility upgrades and renewals. Our comprehensive support ensures the creation of optimal environments.



Reliable Facility Proposals with a Solid Track Record

Built on the same Three Principles of GMP we apply to pharmaceutical plants, our approach to cell processing facilities combines advanced technical expertise with end-to-end project management. From workflow planning to quality assurance, we deliver tailored solutions. Our industry-leading Testing, Adjusting, and Balancing (TAB) capabilities ensure secure, high-performance environments with precise room pressure and aseptic conditions.

**Head Office**

Kayacho First Bldg., 1-17-21 Shinkawa, Chuo-ku, Tokyo, 104 0033
TEL 03-6280-2561

Kobe Sales Office

Sanko Bldg. 7th Floor, 5-1-24 Isokami-dori, Chuo-ku, Kobe, Hyogo, 651 0086
TEL 078-515-6240

<https://skk.jp/en/>

JCR Pharmaceuticals Co., Ltd.

JCR is a **R&D -focused company**.

Guided by our corporate philosophy,

“Contributing towards people’s healthcare through pharmaceutical products,”
we leverage **proprietary biotechnologies**, as well as **cell therapy and regenerative medicine technologies**, to create innovative therapies.

Efforts Toward Development of Cell Therapy and Regenerative Medicine Technologies

JCR is dedicated to developing novel therapies for diseases
that are difficult to treat with conventional therapies.

■ TEMCELL® HS Inj. - Human (allogeneic) bone marrow-derived mesenchymal stem cells



Japan’s first allogeneic regenerative medical product

- ◆ Indication: Acute GVHD following hematopoietic stem cell transplantation
- ◆ Coraborated with MEDIPAL HOLDINGS CORPORATION in the joint development and operation of an ultra-low cold chain system.
- ◆ Since its launch in February 2016, continuously used in clinical practice, totaling 1,000 cases by 2021.



Since its launch in January 2021,
the Bio Research Center has focused on ATMPs
(Advanced Therapy Medicinal Products).



JCR Pharmaceuticals Co., Ltd.

Headquarters: 3-19 Kasuga-cho, Ashiya, Hyogo 659-0021, Japan

URL: <https://jcrpharm.com/>

Contact us: ir-info@jp.jcrpharm.com

Cell culture meets QbD

Fully automated cell manufacturing instrument

CellQualia™ INTELLIGENT CELL PROCESSING SYSTEM



Joint development with the Foundation for Biomedical Research and Innovation (FBRI) at Kobe

 Foundation for Biomedical Research and Innovation at Kobe

- | Automated cell culture from seeding to harvesting
- | Closed system
- | In-line process analysis technologies
- | Auto-sampling for off-line analysis

- | Auto-passaging
- | Real-time imaging
- | Solution Lab in KOBE



Kobe Center for Medical Innovation KCMI (Japan)

More information >

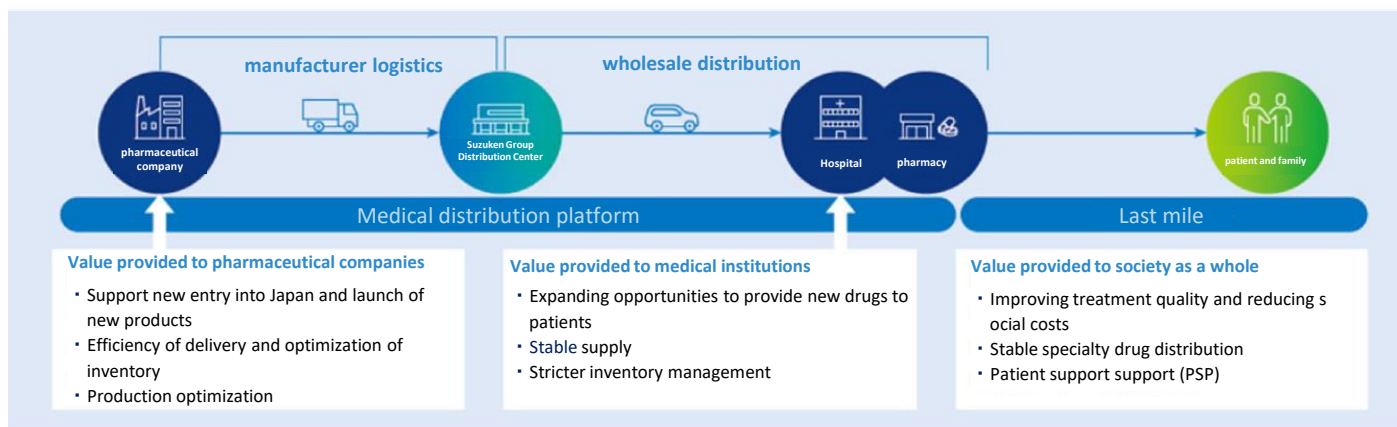
CellQualia™
Official site

www.cellqualia.com



SUZUKEN CO.,LTD.

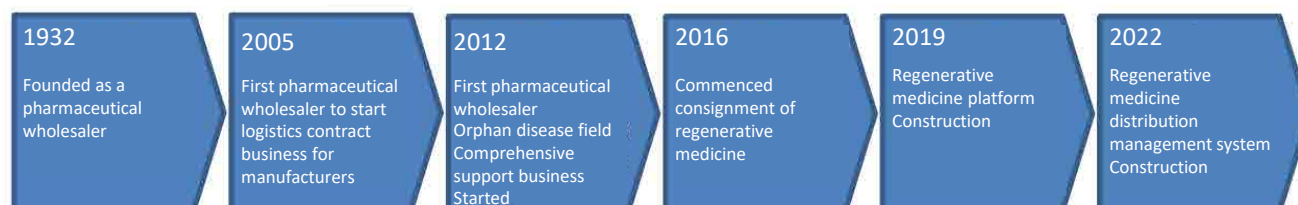
We support the distribution and distribution of regenerative medicine products from clinical trials to commercial products.



[our company's strengths]

1. Logistics: Available for transport and delivery from investigational drug to product launch (direct delivery to medical institutions is also available)
2. Commercial distribution: Available from delivery to medical institutions nationwide to billing and collection agency
3. Information: Distribution management is possible using the patient traceability system "R-SAT"

[Company history]



[News Release]

- May 9, 2022 : Patent obtained for R-SAT, a distribution management and administration schedule support system for regenerative medicine products jointly developed with SanBio Inc.
- May 20, 2020 : Announcement of Consignment of Distribution in Japan of Zolgensma Intravenous Infusion for Gene Therapy for Spinal Muscular Atrophy
- August 5, 2019 : Announcement of Conclusion of Basic Agreement for Distribution of Regenerative Cell Drugs and Commencement of Joint Development of Patient Support System
- May 16, 2019 : Announcement of Consignment of Distribution in Japan of Japan's First CAR T Cell Therapy
- September 25, 2018 : Announcement of Logistics Collaboration in the Regenerative Medicine Products Field between Suzuken and World Courier

[Contact]

In Charge of Regenerative Medicine Products Promotion: Morishita, Nishimura
e-mail) reg_med@suzuken.co.jp

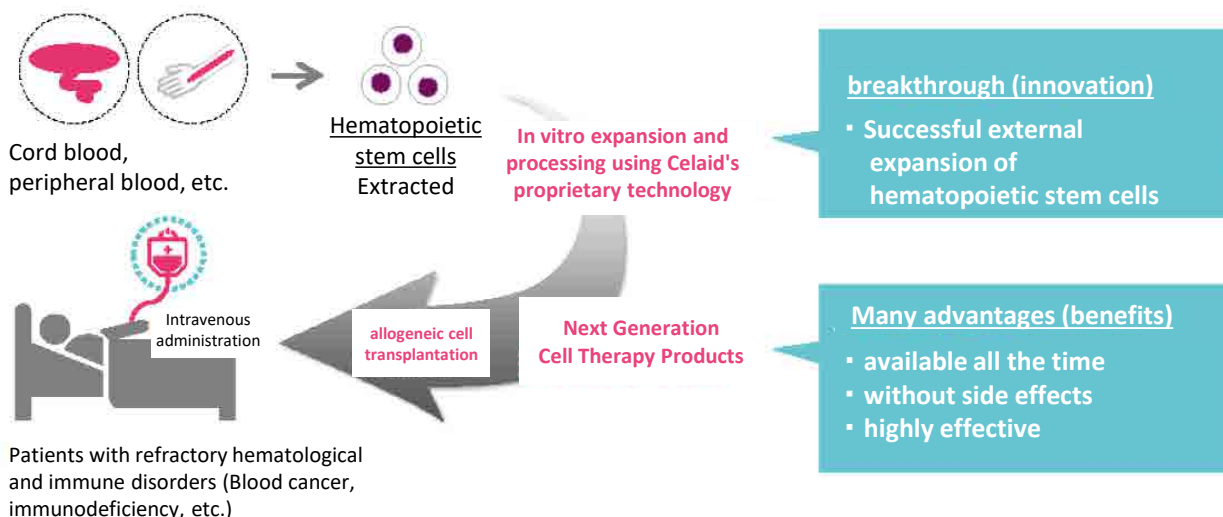
April, 2025



Celaid Therapeutics Inc.

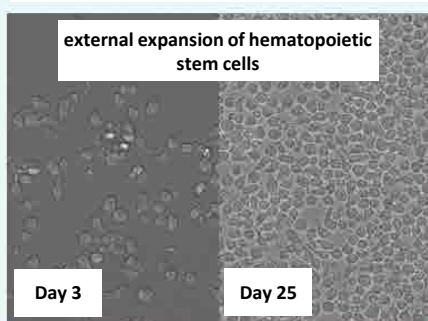
"Changing the Future with Cell Therapy"

Development of new cell therapy products using in vitro hematopoietic stem cell expansion technology



©2023 Celaid Therapeutics Inc. all rights reserved

Celaid Therapeutics is a startup from the University of Tokyo and the University of Tsukuba that has proprietary technology for selective in-vitro expansion of hematopoietic stem cells, the source of human blood. By safely and efficiently increasing hematopoietic stem cells, Celaid aims to provide society with next-generation regenerative medicine products aimed at cell therapy for intractable hematologic and genetic diseases, including hematologic cancers, ex vivo hematopoietic stem cell gene therapy, and angiogenesis for ischemic diseases.



Our company's core technology is capable of expanding human hematopoietic stem cells, which have been difficult to expand in vitro, and selectively expands functional hematopoietic stem cells capable of engraftment while maintaining their undifferentiated state. Our company's cell culture method is a manufacturing method that has succeeded in replacing protein molecules such as albumin and cytokines with synthetic compounds (an international patent application has been filed), making it cost competitive and has the advantage of industrialization that facilitates quality control. It is also expected that the expanded hematopoietic stem cells will be used for gene therapy and other applications.



《 Nobuyuki Arakawa, President and CEO of Celaid Therapeutics Inc. 》

Graduated from Keio University Graduate School of Science and Engineering. Worked as a management consultant at Accenture Corporation. Subsequently, engaged in management of a university-originated biotechnology venture and development of new businesses in the fields of AI, IoT, and healthcare. Co-founded our company in 2020 to provide a new cell therapy method that uses hematopoietic stem cell expansion technology to replace current transplantation methods.

©ContactYamamura, Corporate Administration Division Email contact@celaidtx.com

Daikin Industries, Ltd.

Daikin is a leading company about air conditioning and fluorine chemistry. Daikin contributes to the medical industries.

Fluorochemical

Various materials utilizing fluorine characteristics are used in medical devices

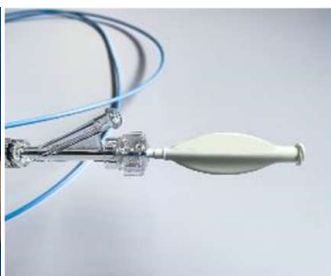
Air conditioning

(engineering)



Endoscope

Fluoropolymer, Fluoroelastomer
Fluorocasting



Catheter

Fluoropolymer, Fluorocasting



Biomedical robot

Fluoroelastomer, Fluorocasting



Total Engineering

Daikin Applied Systems

Solutions for Regenerative Medicine (Daikin Industries, Ltd., Chemical Division)

- Fluorine materials resistant to hydrogen peroxide gas sterilization
- Cell cryopreservation container (under development)

➤ Website

<https://www.daikinchemicals.com/solutions/industries/life-sciences.html>



[Companies developing cell pharmaceuticals]

Please evaluate our cell cryopreservation containers that can be stored at very low temperatures.(-198℃)

Total Engineering of Pharmaceutical Manufacturing Facilities (Daikin Applied Systems, Ltd.)

- GMP compliant CPC, clean rooms, etc.
- For optimal and effective construction and renovation for our
Our unique total engineers with the cooperation of specialize
We propose rings.

➤ Website

https://www.daps.co.jp/case_study/category_index?id=126&category_index_id=126



For more information, please contact Foundation for Biomedical Research and Innovation at Kobe.

The Daidan Group provides both hardware and software support for the field of drug discovery, manufacturing, and treatment in regenerative medicine.



Facilities

Building a flexible manufacturing environment with short delivery times

Clean Booth, CPF



Cellab Healthcare Service Co., Ltd. *

cell manufacture

Eliminating human resource shortages

cell culture contract



Acquisition of license for manufacturing regenerative medicine products

* Subsidiaries specializing in healthcare

Product lineup

nonclinical ► Clinical ► clinical trial ► Treatment

Laboratory animal rearing rack



iRack® System

clean booth



Air Barrier Booth®

Cell culture unit



All-in-One CP Unit®

Cell culture processing facility (CPF)



Air Barrier CPF®

operating room



Karatto Ope®



Hybrid Operating Room

Room for immunocompromised patients (sterile room)



Hot Cure®

Services

Cell culture contract service, manufacturing support, facility validation, rental CPF, etc.

Inquiries

Inquiries form (link to Cellab Healthcare Services website) <https://cellabhs.co.jp/inquiry/>

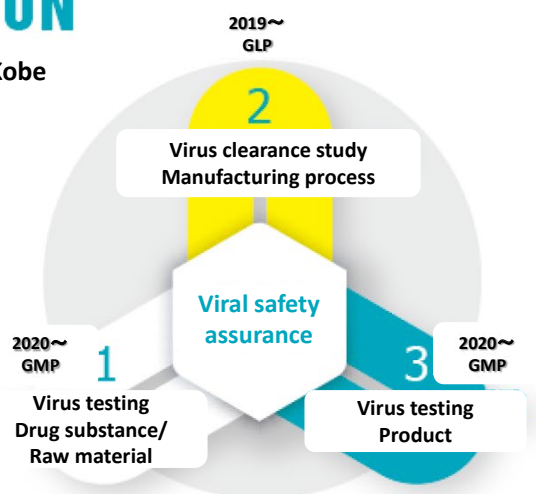
ViSpot Division, Takara Bio Inc.

Your Trusted Partner in Viral Safety Testing for Biologics

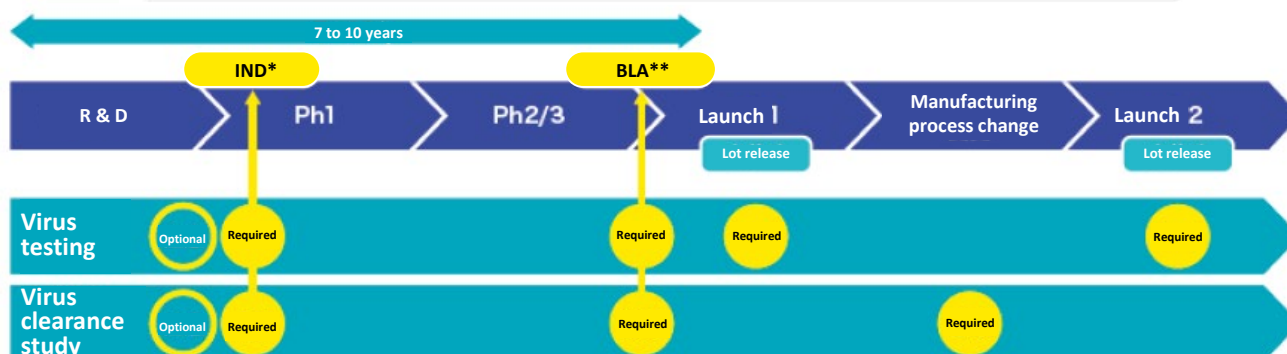
ViSpot MISSION

Viral Safety Testing Service in Kobe

At ViSpot, we are dedicated to advancing biopharmaceutical development in Japan by providing reliable, fast, cost-effective and technically excellent viral safety testing services. We believe you are sure to be satisfied in Kobe.



Virus safety testing supports biopharmaceutical supply chain



* Investigational New Drug Application
** Biologics License Application

Our Laboratories



Kobe Lab

Kobe Center for Medical
Innovation
5-3-6 Minatojima Minamimachi,
Chuo-ku, Kobe, Hyogo 650-0047



Rokko Lab

Asia One Center, 9F
17-1 Koyochi Naka,
Higashinada-ku, Kobe, Hyogo
658-0032



Contact Us

Phone: 078-515-6401

Website:

<https://www.takara-bio.co.jp/research/info/vispot.htm>

Quality/
Analysis/Contract

Contract Research
Organization
(Non-Clinical/Clinical)

Others



TMI Associates



TMI Associates

670+

Attorneys

90+

Patent Attorneys

Our Legal Practice

One-stop comprehensive service backed by both practical and theoretical expertise in the healthcare industry and legal fields

TMI Associates provides clients with exceptional legal services grounded in deep expertise and extensive experience, based on our industry knowledge and technical understanding, which enables us to address complex legal issues in the healthcare business field.



Regulations of Drugs, Devices and Biologics



Medical Regulations



Public Insurance



Research Ethics, Conflicts of Interest



FDA Regulations, Healthcare Compliance in the United States

Extensive expertise on legal issues in the healthcare business sector



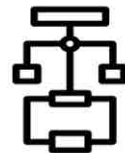
Intellectual Property



Healthcare Data Regulations



M & A, Investments

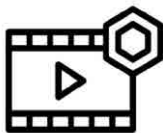


Licensing Agreements, Co-Development Agreements



Startups, IPOs

Integrated team of attorneys and patent attorneys



Advertising Laws



Medical Malpractice, Drug Litigations



Regulatory Response, Investigations



Bankruptcy and Rehabilitation of Medical Institutions



Labor and Employment at Medical Institutions

Global Support Structure

No Cost Legal Consultation

Our law firm provides free legal consultation services to companies and organizations (including medical institutions and research institutions) based in Kobe Biomedical Innovation Cluster or Kobe City to support their business strategies. Our experts provide initial advice on legal issues that arise in business operations and research and development, and suggest appropriate solutions and provide legal advice for avoiding legal risks and promoting their businesses smoothly. Our legal fields are not limited to the foregoing. Please make use of all our services.

Website: https://www.fbri-kobe.org/kbic/event/detail.php?event_id=825

TMI Associates Kobe Office

Address: 12th Floor, Kobe Sannomiya
Hankyu Building, 4-2-1 Kano-cho, Chuo-ku,
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FAX :+81-78-325-5543

Representative Attorney

Takuto Kobayashi
Email: kobe@tmi.gr.jp
HP: <https://www.tmi.gr.jp/>



Patent Offices,
Others

One Stop Provider

Complete Support up to Market and Beyond

GLP Viral Clearance

GMP Viral Safety Testing

GMP Cell Bank Manufacturing



Started as a Spinoff of PASTEUR INSTITUTE created in 1987 Texcell SA was established in 2003



Preclinical

- R&D Cell culture
- Single cell-cloning
- Immuno Bioassay
- NGS



Phase 1

- GMP MCB•WCB Manufacturing
- GMP Safety Testing
- GLP Viral Clearance
- NGS



Phase 2

- GLP Viral Clearance
- Testing Design Optimization
- Immuno Bioassay



Phase 3

- GLP Viral Clearance
- GMP Safety Testing
- Immuno Bioassay



Phase 4

- Batch Release
- Immuno Bioassay
- Potency Assay

Global **Texcell** services pre-clinical/clinical trial to beyond Market Release

Texcell Japan

070-3199-6601

Sales/Director

mjoguina@texcell.fr

JOGUIN Matthieu

Technopro R & D Co., Ltd. Kobe Research Center








For research and development of regenerative medicine drugs, cells, devices, and technologies
Please use Technopro R & D's contract research and experiment service!

Features of our company contract service


- **Wide range of support areas** We can handle a variety of tests, from molecular to animal experiments!
- **Many contracts** We contract more than 300 tests per year!
- **High trust** Many customers use our service multiple times!

[Brokerage Services]

In addition to the following, we can handle a wide range of tests according to your requirements. Please feel free to contact us.

Group	corresponding technology	Specific test examples
gene 	<ul style="list-style-type: none"> Plasmid design and preparation (Forced generation, gene editing, etc.) Virus design and preparation (Lentivirus, AAV, etc.) Mutation and sequence analysis 	Viral plasmid construction (From 1.2 million yen, delivery time around 3 months) DNA fragments are spliced together in budding yeast to prepare a plasmid containing the viral genome (>20kb) without infectivity.
protein 	<ul style="list-style-type: none"> Expression purification of recombinant proteins Protein purification from biological samples Peptide synthesis Analysis of protein and peptide properties 	Protein array construction (From 4 million yen, delivery time around 3 months) Protein arrays composed of arbitrary protein groups are constructed using a wheat germ cell-free system.
cell 	<ul style="list-style-type: none"> Cell culture (Primary cultures, three-dimensional skin models, cell lines, etc.) Cell production (Gene editing, knockdown, forced expression, etc.) Expression analysis (Real-time PCR, Western blot, etc.) Functional analysis (Proliferation, cell death, phosphorylation, differentiation, etc.) 	Gene KO cell construction (From 2.5 million yen, delivery time around 5 months) Guide RNA for the specified gene is designed using CRISPR/Cas9 system, and knockout (KO) cells are constructed.
Equipment and reagents 	<ul style="list-style-type: none"> Inspection of culture equipment (Cell adhesion, endotoxin test, etc.) Evaluation of equipment (Performance evaluation, protocol development, etc.) Evaluation of experimental reagents (Performance comparison with other companies' products, third-party evaluation, etc.) 	Endotoxin test (From 340,000 yen, delivery time about 1 month) Eight culture-related instruments are tested for the presence of endotoxin.
Screening 	<ul style="list-style-type: none"> Cell-free assay (TR-FRET, HTRF, AlphaScreen, etc.) Cell-based assay (Luciferase, NanoBit, etc.) 	Inhibitor screening (From 6 million yen, delivery time around 2 months) The HTRF reaction system is used to measure protein-protein interactions. Add each of the 500,000 compounds provided and measure the reaction.
natural product purification 	<ul style="list-style-type: none"> Crushing and extraction (Crushing of raw materials, removal of precipitates, extraction and concentration) Purification (Separation, precipitation, recrystallization, chromatography, etc.) 	Glycolipid purification (From 2.5 million yen, delivery time around 2 months) Purification of 5 g or more of specific glycolipids from plant materials by organic solvent extraction and various chromatography (purity ≥ 95%).
MEA 	<ul style="list-style-type: none"> Neurotoxicity/pharmacology evaluation in iPSC neurons AI & MEA-based Drug Safety/Pharmacology 	Correlation between neurotoxicity risk assessment and animal studies (6 million ~, delivery time around 4 months) Human iPSC neurons were exposed to test substances and positive/negative control compounds. The data obtained were analyzed by AI to evaluate the central toxicity profile.

More information: <https://www.technopro.com/rd/services/contract/>

 Commissioned research and experiments in the biotechnology and pharmaceutical fields

[Contact]

Masahiko Hirooka, Technopro Technopro R & D Kobe Research Center

Kobe International Business Center 505, 5-5-2 Minatoshima Minami-cho, Chuo-ku, Kobe, Hyogo 650 0047

Tel: 078-304-7581

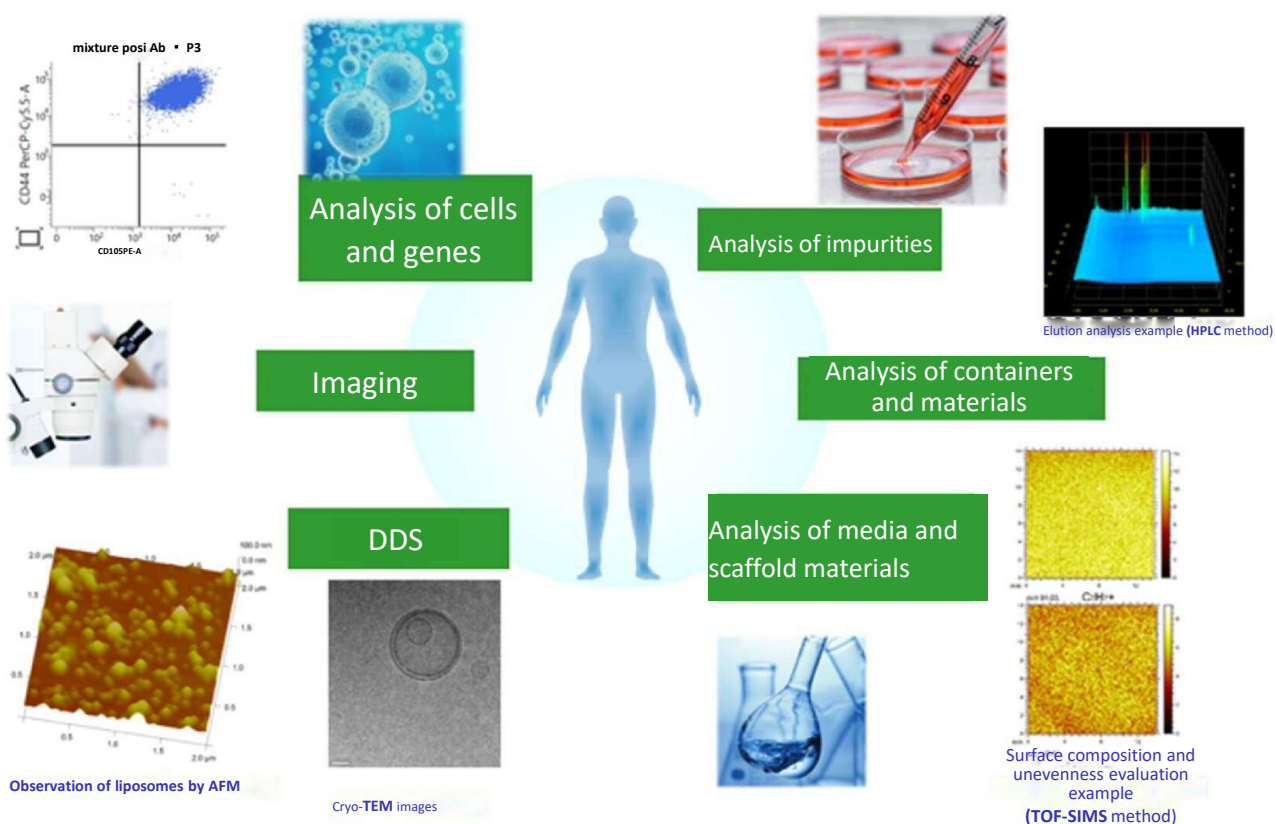
E-mail: Hirooka.Masahiko@technopro.com

Toray Research Center, Inc. (TRC)

TRC is an expert in analytical technology.
TRC provides various analytical and evaluation services for regenerative medicine products such as cell and gene therapy drugs.

Technology & Trust: Contributing to Society with Advanced Technology

Since becoming independent from the research and development division of Toray Corporation in 1978,
TRC assists customers in innovation and problem solving through analytical technology support.



Regenerative medicine: https://www.toray-research.co.jp/analysis-evaluation/ana_032.html

mRNA Pharmaceuticals: https://www.toray-research.co.jp/analysis-evaluation/ana_065.html

* **Contact:** <https://www.toray-research.co.jp/>

Life Science Sales Department Tel:03-3245-5666

Life Group, Kansai Sales Department Tel:077-533-8689

Email : bunseki.trc.mb@trc.toray

TOPPAN Inc.

[Corporate Profile] Creating new value by overcoming all social issues

- Business domain -

INFORMATION & COMMUNICATION

Creative communication and information management

LIVING & INDUSTRY

Living and industrial materials and functional materials

ELECTRONICS

Electronic devices and devices



【Specific initiatives in the medical and pharmaceutical fields】

Becoming a leading company solving social issues worldwide through DX and SX

① Enhancing functionality, environmental friendliness, and value through sustainability-conscious packaging (SX)

◆ In-vitro diagnostics manufacturing contract business

- Our manufacturing contract business is underway at our manufacturing base in **Kasai City, Hyogo Prefecture**.
- We are expanding our scope beyond in-vitro diagnostics.



② "DX Solutions" to solve problems at medical institutions and enable DX in medical care

◆ Support for DX in medical care

- Development of **IC tag labels** that can be used in **frozen environments**
- Improvement of operations with **IC tag systems**
- Realization of paperless and real-time systems using **electronic paper**
- Visualization of temperature management using **on-tray system tags**



③ Contributing to the realization of future medical care through social implementation of new healthcare technologies

◆ 3D cell culture invivoid®

Innovative for next-generation drug discovery Tissue engineering technology

◆ Digital ICA® High-Sensitivity Fluorescence Detection Technology

Detecting DNA and other biomolecules by distributing them one molecule at a time

◆ Films that can be applied to the skin

Films that can be applied directly to the skin and can be printed (designed) on the surface



If you want to solve on-site problems with DX and SX, please leave it to TOPPAN!

TOPPAN Corporation

Consumer & Industrial Business Division

Promotion Office, SX Business Development Division

Hitoshi Manabe

MOBILE : 080-2467-1837

Nakanoshima Festival Tower, 2-3-18 Nakanoshima, Kita-ku, Osaka 530 0005, Japan

SX Business Promotion Center Healthcare Business

email : hitoshi.manabe@toppan.co.jp^[LINK1]

TOPPA!!!
TOPPAN

URL:<https://www.toppan.com/ja/>



Custom Synthesis by NARD institute, LTD.

We aim to solve your problems, we conduct research and development support.

- ❑ Synthesis of non-commercial compounds
- ❑ Design of original functional molecules
- ❑ Manufacturing under ISO standards and GMP guidelines

Technical keywords

- Compounds for media supplementation
- Fluorescent labeling
- Cell scaffolding Material
- Hydrophilic polymer
- Hydrogel
- Pharmaceuticals
- Manufacturing Process Development

◇ FTE research contract

◇ Scale-up production*

*Conducted at NARD Chemicals, Ltd.

NARD Institute, Ltd.

Corporate Research Department

2 -6 -1 Nishinagasu-cho, Amagasaki-shi, Hyogo 660 0805

TEL: 06-6482-7024

<https://www.nard.co.jp/>

Please feel free to contact us for your request!



Nissin Corporation

Company Profile

Yokohama Head Office: 6-81, Onoe-Cho, Naka-ku, Yokohama, Kanagawa

Tokyo Head Office: 1-6-4, Kojimachi, Chiyoda-ku, Tokyo

Founded: December 14, 1938 (Showa 13)

Capital: 6,097million yen (as of March 31, 2024)

Business: International transportation, domestic transportation, warehousing, customs clearance, moving, travel, etc.

Number of domestic locations: 127 (as of March 31, 2024)

Number of overseas locations: 24 countries 150 offices (31 local subsidiary) (as of the end of March 2024)

Service Overview

- Domestic temperature control truck transportation
- International GDP transportation (air and sea)
- Domestic/Overseas thermal packaging
- Exhibition transportation
- Trade consulting (export/import consultation)
- Export/Import customs clearance
- **Pharmaceutical** storage in GDP-certified warehouses



Nissin in fiscal 2024

We opened VIXELL temperature control stations in New York and Singapore
Many companies have used VIXELL for international transport of cells
We have also begun efforts to obtain a license for pharmaceutical manufacturing in the Kanto region

Service performance

- Investigational drug GDP transport by constant temperature trucks
- Long-term temperature maintenance transport using Panasonic's VIXELL ® (temperature logger with GPS function)
- Marine transport of pharmaceuticals using Reefer Container
- Transport of products exhibited at medical exhibitions
- Accompanying consultations with customs and authorities
- Consulting on how to fill out documents in the field of trade practice and acquisition of regulatory authority
- Wholesale distribution business license and drug tax increase license Storage in warehouse (acquisition of GDP certification)
- Thermal storage agent temperature control service

DX Promotion Department, Pharmaceutical Business Promotion Section, Nissin Corporation

Tsuyoshi Shijyuubou, Yasushi Maegawa

1 -6 -4 Kojimachi, Chiyoda-ku, Tokyo 102 8350

Tel:03-3238-6549

mailto: nissin_medical@nissin-tw.com

<https://www.nissin-tw.com/>

What we would like to consider in the medical field

Validation of international transport of cells by multiple companies



Bridging Good Faith and Healthcare

Through blood products derived from voluntary non-remunerated blood donations, we contribute to people's health with the highest sense of ethics and responsibility.

Purpose of Establishment

Delivering voluntary non-remunerated blood to patients in a safe and secure form. This is the mission of those involved in the blood service that never changes. We placed the highest priority on enhancing the safety and reliability of plasma fractionated products, aiming to achieve domestic self-sufficiency and stable supply through donated blood. Our operation was launched on June 1, 2012 and commenced on October 1 of the same year. Based on the basic idea that blood should not be sold commercially, we will pave the way for a new history of the plasma fractionation business as a non-profit-making general incorporated association. As those who handle blood products made from voluntary non-remunerated blood, we aim to be an organization that protects the health of the people with a high sense of ethics and responsibility.

R&D

We manufacture plasma fractionated products by pooling valuable plasma from blood donors, and are pursuing the potential of blood products from limited resources. Since human blood is used as a raw material, it is necessary to reduce the risk of viral infections as much as possible, especially regarding safety. Therefore, we have established a laboratory dedicated to research safety measures against infectious pathogens.

Structure of the Central Research Laboratory

Protein Chemistry Research Section: Development of specific isolation and purification methods for functional proteins
that are candidates for new products

Protein Pharmacology Research Section: Research on the efficacy, safety, and pharmacokinetics of functional proteins

Infectious Pathogen Research Section: Research on the safety of plasma fractionated products against infectious pathogens

We create new value from donated blood.

As part of our pursuit of the potential of limited resources, we are seeking opportunities to apply plasma components to regenerative medicine substrates. We will also contribute to efforts toward commercialization by applying our experience, knowledge, and technological capabilities in virus safety.



Contact:

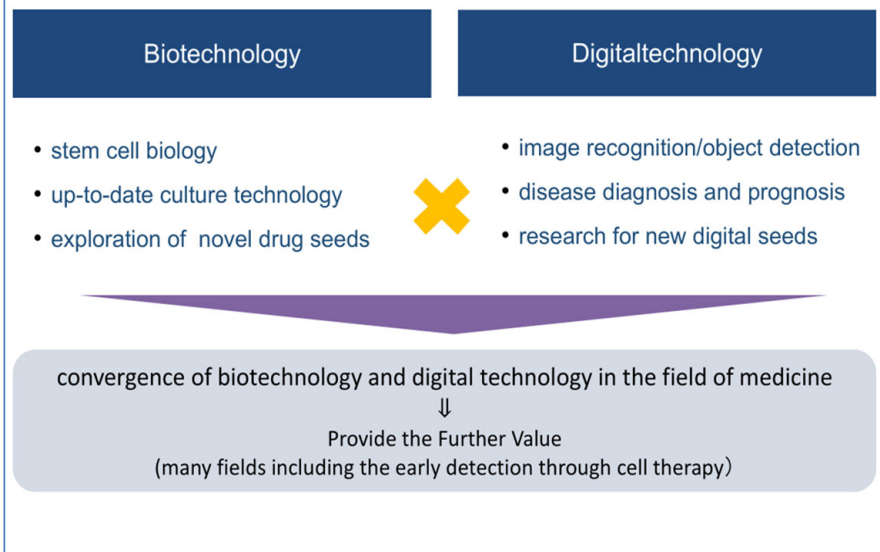
Central Research Laboratory, Japan Blood Products Organization
Kobe KIMEC Center Building 8F, 1-5-2 Minatojima-minamimachi, Chuo-ku, Kobe, 650 0047
TEL: 078-599-5095/email: info-jb-reslabo-gr@jbpo.or.jp
URL: <https://www.jbpo.or.jp/>

NextGeM Inc.

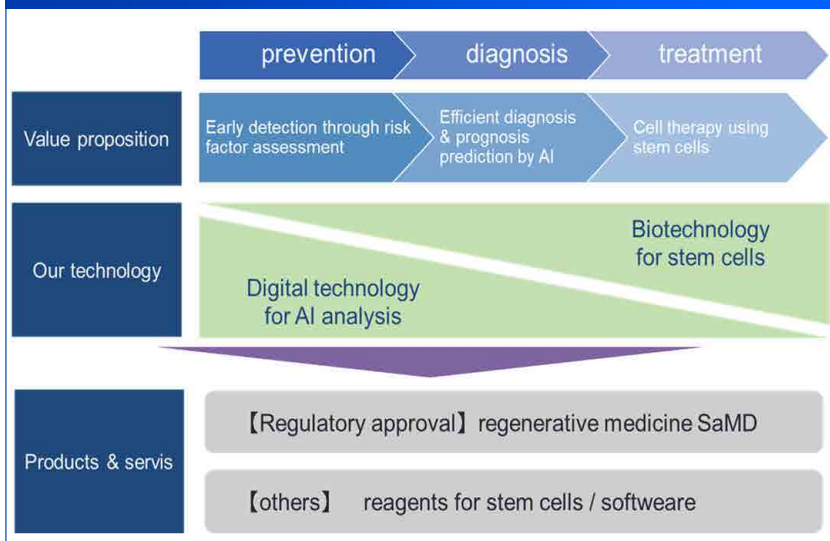
Biotechnology and digital technology can create valuable solution on their own.

Moreover, we believe that the convergence of biotechnology and digital technology can provide optimal solutions to serious medical needs.

Business Concept



Business Domain



We are developing solutions required in each step of “prevention,” “diagnosis,” and “cell therapy” in medicine. Digital technologies such as AI analysis are mainly used for prevention and diagnosis, while biotechnologies for stem cells are mainly used for diagnosis and cell therapy.

NextGeM provides innovative products and services with a fusion of stem cell-related biotechnology and the digital technology of AI machine learning.

NextGeM Corporation strives to develop groundbreaking technologies and products by promoting cutting-edge science and hiring and training talented individuals.

Tokyo Data Lab: 5- 13, Jinnan 1-chome, Shibuya-ku, Tokyo
 Kobe Wet Lab : 6-3-5, Minatoshima Minamimachi, Chuo-ku, Kobe
 URL: <https://nextgem.jp/> Contact: info@nextgem.jp



Vision Care Group

For the benefit of patients with retinal diseases from Kobe to the world

Utilizing research results of the world's first iPS cell-based retinal cell transplantation to develop new treatments

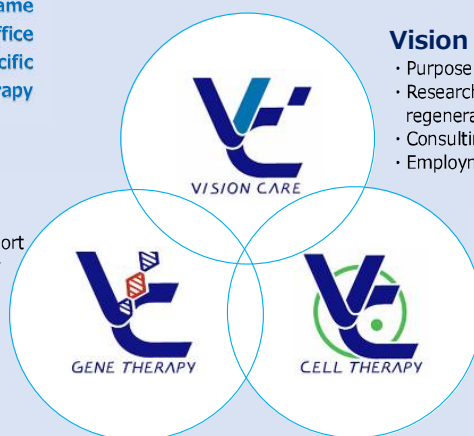
The Vision Care Group, which develops treatments for retinal diseases, was established based on the Kobe Eye Center concept proposed by President Masayo Takahashi and fellow ophthalmologists to advance the patient well-being employing state-of-the-technologies including those from her RIKEN teams. As subsidiaries for specific purposes, VCGT Inc. was established in August 2020 and VCCT Inc. in March 2021, focusing on the commercialization of gene and cell therapies, respectively. With the mission of "A cure for all outer retinal diseases", we are conducting joint research with Kobe City Eye Hospital. In addition to promoting research and development for the realization of gene therapy and regenerative medicine, and bringing our research technology to practical use, we are also working to create new businesses as a liaison for the Eye Center.

Vision Care Inc. performs the same research division as the head office functions, and the purpose specific subsidiary of gene and cell therapy functions.

VCGT Inc.

- Gene Therapy Development
- Manufacture, sales, export and import of products related to gene therapy
- Acquisition, ownership, licensing, transfer, and management of intellectual property such as industrial property rights and copyrights.

*RIKEN Venture Certification



Vision Care Inc.

- Purpose Management of subsidiaries
- Research and development in ophthalmology and regenerative medicine
- Consulting in ophthalmology and regenerative medicine
- Employment and livelihood support for low vision

VCCT Inc.

- Cell Therapy Development
- Manufacture, sales, export and import of products related to regenerative medicine
- Acquisition, ownership, licensing, transfer, and management of intellectual property such as industrial property rights and copyrights.

*RIKEN Venture Certification

Development pipeline

Product	Cell and genetic technology
MastCT-01,03	Allogenic iPS cell-derived retinal pigment epithelium (RPE)
MastCT-02	Autologous iPS cell-derived retinal pigment epithelium (RPE)
MastCT-04,05	Retinal sheet derived from allogenic iPS cells
MastGT-01	Retinitis pigmentosa gene therapy



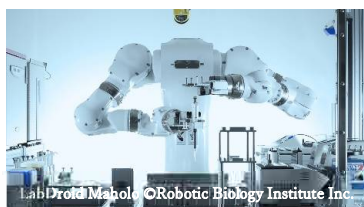
The development number "Mast" was named in the hope that it will become a mainstay in the treatment of outer retinal diseases and advance in the ocean of medicine.

<Release>

- 2025.01.14 VCCT Inc. and Japan Tissue Engineering Co., Ltd. sign a capital and business alliance for commercialization of regenerative medicine products using iPS cells
- 2024.12.24 VCGT Inc. raises 100 million yen from Ritsumeikan Social Impact Fund to develop gene therapy for extremely rare diseases
- 2024.09.25 VCCT Inc. selected as the Ministry of Economy, Trade and Industry's 2024 International Development Program for Healthcare Industry



Kobe Eye Center



LabDroid Maholo ©Robotic Biology Institute Inc.



Cell processing center FiRst



Kobe Eye Center Vision Park

Vision Care Group <https://www.vision-care.jp/>

Address : Kobe Eye Center 5F, 1-8, Minatojima-minamimachi, Chuo-ku, Kobe, 650-0047
(Inquiries) info@vision-care.jp



Hitachi, Ltd. R&D Group

To advance the spread of regenerative medicine and cell therapy, there is a growing need for technologies that automate manual cell culture processes and consistently produce high-quality cells at a reasonable cost. Hitachi aims to address this challenge by leveraging cell automation, starting with the establishment of the Hitachi Kobe Laboratory in April 2017. Taking advantage of its strategic location, Hitachi launched the iACE2 automated cell culture system in 2019, actively pursuing open innovation. The iACE 2 system enables large-scale cell cultivation, with its single-use, closed channel module ensuring high sterility. Hitachi is committed to support the growth of the regenerative medicine and cell therapy fields by providing comprehensive solutions across the entire Hitachi Group.

The iACE 2 automated cell culture system

Regenerative medicine is transitioning from research to practical application. The iACE2 system, an automated platform leveraging iPS cells, is poised to lead the field of regenerative medicine. It is expected to become a strong leader in iPSC-based regenerative therapies.



Stable production of high-quality cells via automated cell culture

- ☑Achieving mass cell culture ☑Automating the expansion and differentiation of iPS cells
- ☑Ensuring a sterile environment with a single-use closed system module

Reference

- iACE2 automated cell culture system
<<https://www.hitachi.co.jp/products/healthcare/products-support/regenerative-medicine/index.html>>
- The Challenge of Cell Mass Production, the Key to Regenerative Medicine
<https://social-innovation.hitachi/ja-jp/case_studies/hitachi_kobe_lab/>
- Design Cells: Designed Cells Cure Diseases
<<https://social-innovation.hitachi/ja-jp/article/designed-cell/>>
- Creating Next Generation Regenerative Medicine and Cell Therapy Technologies and Systems
<<https://www.hitachi.co.jp/rd/sc/story/medical/index.html>>
- iACE 2 Automated Cell Culturing System Supporting Collaborative Development with Companies in Kobe Medical Industry
<<https://www.fbri-kobe.org/kbic/cases/cs008/>>
- Regenerative Medicine Enabling Fundamental Therapeutics and Supporting Automated Culturing Technology, Mitori Kato et al.,
Hitachi Review vol. 102 No. 05 89 -94 (2020)
<https://www.hitachihyoron.com/jp/archive/2020s/2020/05/05b02/index.html>

*iACE is a registered trademark of Hitachi in Japan

*Part of the contents introduced in this article were performed at the Japan Agency for Medical Research and Development (AMED) "JP 18be0104016".

Hitachi Kobe Laboratory, Research and Development Group, Hitachi, Ltd.
Address: 6-3-7 Creative Lab Kobe Suite 304, Minatojima-minamimachi, Chuo-ku, Kobe, Hyogo 650 0047
Contact: Hiroko Hanzawa (070-3952-5338/hiroko.hanzawa.hr@hitachi.com)



PHICELL

PHICELL Corporation
Kobe KIMEC Center Building 2nd Floor
1-5-2 Minatojima-minamimachi,
Chuo-ku, Kobe



PHICELL for Cryogenic Storage

Proven solution
for specimen storage and
logistics management

The external tank offers a reassuring capacity –

1,000 times the volume than the storage tank.

Uninterrupted operation - 24-hour automatic liquid
nitrogen refilling with **100%** annual uptime.

More than 100,000 samples stored, including a
wide range of cellular materials.

Contract Research
Organization
(Non-Clinical/Clinical)

Logistics

Others

Bourbon Corporation

[Overview of Initiatives/Related Products]

As part of our health science research, Bourbon is developing a pluripotent stem cell research program. Utilizing our extensive knowledge of culture techniques focusing on sugar, a major food component, we are developing safe and reliable fundamental technology to control cell proliferation using appropriate and optimized sugars to support the advancement of regenerative medicine research.

Based on the core technology, our group company, Bourbon Biomedical Advanced Research Laboratories, Inc., has developed the **Xyltech™** series of regenerative medicine reagents. The **Xyltech™** series is a new culture media system that controls the rate of cell proliferation. We added a new series of animal-free culture media for human mesenchymal stem cells.

[Product lineup]

Human pluripotent stem cells



Human pluripotent stem (iPS/ES) cells

Proliferation Control Medium
Xyltech™ BOF-01

Human fibroblasts

Material qualification certificate for regenerative medicine products obtained



Serum-free culture medium for human fibroblasts [Cell proliferation suppression]

Xyltech™ H-Fbro-01

Serum-free culture medium for human fibroblasts [Cell proliferation]

Xyltech™ Growth H-Fbro

Human mesenchymal stem cells



Serum-free culture medium for human mesenchymal stem cells [Cell proliferation suppression]

Xyltech™ MSC-01 Xeno-Free
Xyltech™ MSC-02 Animal-Free

Serum-free culture medium for human mesenchymal stem cells [Cell proliferation]

Xyltech™ Growth MSC

◇ For information about Xyltech™ series culture medium, please visit the following website ◇

ブルボン再生医科学研究所

Bourbon Biomedical Advanced Research Laboratories, Inc.

HP: <https://www.bourbon-barl.co.jp/>^[LINK1]

Contact : support@bourbon-barl.co.jp^[LINK1]

[Contact]

BOURBON Corporation, Advanced Research Institutes,
Laboratory for Advanced Health Sciences,
Sakiko Takizawa
TEL: 0263-88-7848
E-mail: takizawa-sak@bourbon.co.jp

BOURBON
ブルボン



VectorBuilder

Revolutionize Gene Delivery

From Research to Therapy Leveraging Cell and Gene Therapy Drug Development

VectorBuilder CDMO service:

VectorBuilder is a full-service Contract Development and Manufacturing Organization (CDMO) with extensive expertise and technology in manufacturing GMP-grade viral, non-viral, RNA vectors for needs in Gene and Cell therapy and regenerative medicine.

VectorBuilder provides wide spectrum of services from vector design, manufacturing, QC, Fill/Finish, QA, IND support, technology transfer, and to commercial manufacturing services. VectorBuilder's expert vector development team designs and manufactures various vectors from research grade and preclinical grade vectors to full GMP-grade vectors. We have track records of providing development and manufacturing of thousands of cell and gene therapy viral, non-viral and RNA vectors worldwide.

VectorBuilder GMP facilities:

From fully complianced ICH guidelines and EU regulatory standards facilities, we operate state-of-the-art GMP facilities to meet our global clients' needs. We offer GMP grade plasmid DNA, AAV, lentivirus, Adenovirus, oncolytic viral vector, Retrovirus and and IVT RNA on a wide range of scales.



VectorBuilder is recognized worldwide



VectorBuilder Honored with 2025 CDMO Leadership Award For CGT Global Category

VectorBuilder, a global leader in gene delivery and technology, proudly announces that it has been awarded the "CDMO Leadership Award - Cell & Gene Therapy, Global Category" in the annual selection jointly hosted by Outsourced Pharma and Life Science Connect. The award recognizes VectorBuilder's performance in key areas such as quality, reliability, and technical capability.

<https://en.vectorbuilder.com/about-us/newsroom/vectorbuilder-honored-2025-cdm-leadership-award.html>

Quality/
Analysis/Contract

Contract Research
Organization
(Non-Clinical/Clinical)

VectorBuilder Inc.

Global headquarter

1010 W. 35th street, Suite 515, Chicago, IL 60609, USA

Japan headquarter

2-12-16, Shin-Yokohama, Kouhoku-ku, Yokohama, Kanagawa, Japan

Kobe office

1-5-2 Minatojima Minami-machi, Chuo-ku, Kobe, Hyogo, Japan

✉ : service-jp@vectorbuilder.com <https://www.vectorbuilder.jp/>



Please contact us:

Affordable cost, short TAT and comprehensive services

We have a seed drug, develop it robustly and efficiently

Yes , We do custom for your Unique gene delivery development!

Others



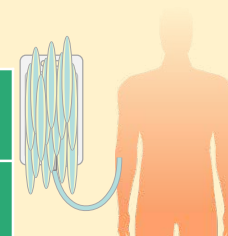
HEALIOS K.K.

Our mission is to foster a “Life Explosion” that enriches the lives of people around the world. In pursuit of this mission, we maintain the goal of delivering cures and hope to patients with unmet medical needs.

Somatic Stem Cell Regenerative Medicine

【Inflammatory Conditions】

HLCM051	ARDS	Invimestrocel	Global (USA)	Japan: Japan: Conditional and Time-limited ARDS Approval Application in preparation
	Ischemic Stroke			Global: Preparing for Phase 3 study
				Japan: Aiming for Conditional and Time-limited Approval Application
				Global : Fast Track and RMAT Designation

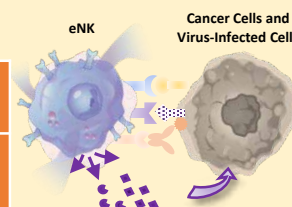


Development of cellular pharmaceuticals for Acute Respiratory Distress Syndrome (ARDS) and Ischemic Stroke using the stem cell product HLCM051.

iPSC Regenerative Medicine

【Immune Oncology】

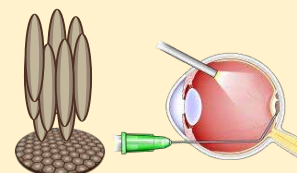
HLCN061	Solid tumors	eNK	Global	Akatsuki Therapeutics leads research and development
—		CAR-eNK	Global	



Research and development of cancer therapies using engineered NK cells (eNK cells) with enhanced anti-cancer activity by combining iPS cell technology and gene-editing technology.

【Replacement Therapy】

HLCR011	RPE Tear Age-related Macular Degeneration	Retinal Pigment Epithelium (RPE)	Japan	Joint development with RACTHERA Co. Ltd.
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• iPSC Platform

Development of allogeneic iPS cells (Universal Donor Cell: UDC) with minimized immune rejection risk irrespective of HLA type, leveraging gene-editing technology.



Differentiation and induction of various cells from iPS cells to develop new treatment methods for intractable diseases.

Company Overview

Company Name	HEALIOS K.K. (Tokyo Stock Exchange Growth Market Securities Code: 4593)
Head Office	Hibiya Mitsui Tower 12F, WORK STYLING, 1-1-2 Yurakucho, Chiyoda-ku, Tokyo 100-0006, Japan
Kobe Research Institute	Kobe KIMEC Center Bldg. 3F 1-5-2 Minatojima-Minamimachi Chuo-ku, Kobe, Hyogo 650-0047, Japan
URL	https://www.healios.co.jp/
Contact	info@healios.jp

2025.05

MATRIXOME

Creating the Future of Regenerative Medicine

iMatrix



perLAM



Innovating the next generation of cell culture with Laminin E8 fragments and perlecan-conjugated laminin E8

- Our unique lineup of substrates comprehensively covers the entire Laminin α -chain domain
- Superior performance in adhesion, proliferation, and differentiation efficiency compared to conventional substrates
- Trusted by researchers worldwide — from basic research to GMP-compliant clinical grade applications

Matrixome, Inc.

Sales Department: Apurva K.
TEL: 06-6877-0222



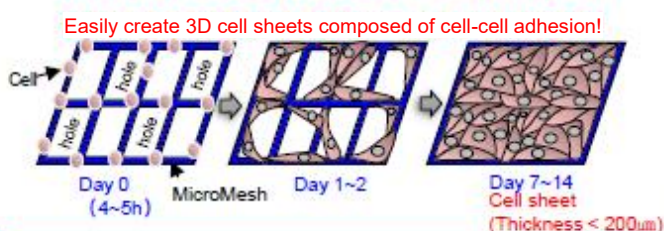
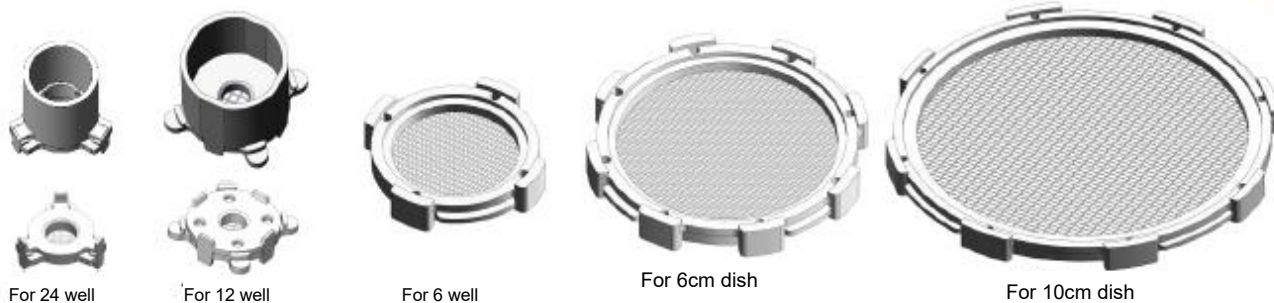
For product inquiries, please contact us on our website.



Micro mesh cell culture device

(メッシュテーブル)

Meshtable®

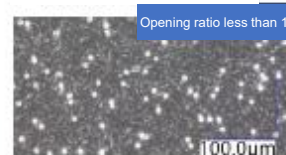


Mesh Details



Mesh Material: Polyester 100%
Thickness Approx. 10µm
Opening Dimensions Approx. 150 x 50µm

General Membrane



10,30 Mm Opening Dimensions d0.4~8µm

[Features of Meshtable®]

- Cell sheet formation maintained by cell-cell adhesion is possible.
- Compared to normal flat culture, **cell function is expected to be improved**.
- Long-term continuous culture is possible in the state of cell mass** (* depends on cell type)
- Micro-mesh-cultured cells can be easily desorbed with the mesh.
- Micro-mesh-cultured cells can be observed from both sides (flipped).
- Applicable to existing well plates and dishes, and easy to observe with a general inverted microscope, etc.

Mizuta Seisakusho Co., Ltd. Click here for the Biomedical Business website.

<https://www.biomedical.mizuta-inc.com/>
6-3-7 Minatojima-minami-cho, Chuo-ku, Kobe, Hyogo,
650 0047

Creative Lab Kobe (CLIK)

Room 321

Fujino Ishihara Kitano
mail: meshtable@mizuta-inc.com

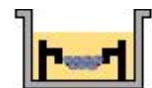


[Results of Research and Culture (Cell Type)]

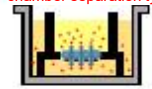
Cell type	Long-term culture record
NHDF	Human adult skin fibroblasts
NHEK	Human adult epidermal keratinocytes
HepG2	Human hepatoma-derived cells
Tig-120	Human normal diploid fibroblasts
Caco-2	Human colon cancer-derived cells
hMEC/D3	Human brain capillary endothelial cells
C2C12	Mouse myoblast cell line
hMSC	Human mesenchymal stem cells 88days
HCM	Cardiac muscle cells 264days
HUVEC	Umbilical vein endothelial cells 145days
Carmy-A	Human iPS-derived cardiomyocytes 101days
Tig-120+HUVEC	Co-culture record
HCM+HUVEC	Synchronous beating duration 500 days
hMSC+HUVEC	172 days

[Initiatives for Various Applications]

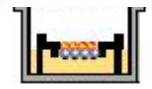
•Evaluation of chemical metabolism



•Evaluation of chemical permeability (upper and lower chamber separation type)



•For various co-cultures



Air-liquid interface culture

• Scaffold of gel



For 12well/24 well



3 types co-culture

• For bioreactor



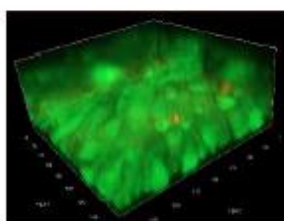
• Large cell sheet for regenerative medicine



secreted substances interaction

[Culture Example]

[HCM (Human Cardiomyocyte)]



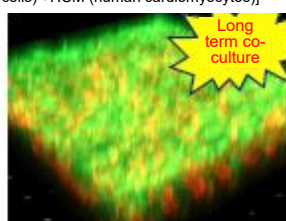
Oriented culture
264 days

[NHDF
(Human adult epidermal keratinocytes)]



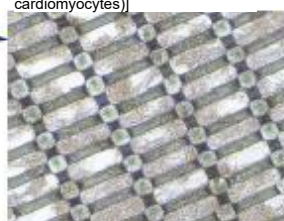
Day 29
73 days culture

[HUVEC (human umbilical vein endothelial cells) +HCM (human cardiomyocytes)]



2 layer seeding (co-culture)
500 day culture

[Carmy-A
(human iPS-derived cardiomyocytes)]



101 day overall beating (Last about once/3 seconds, all synchronizations)

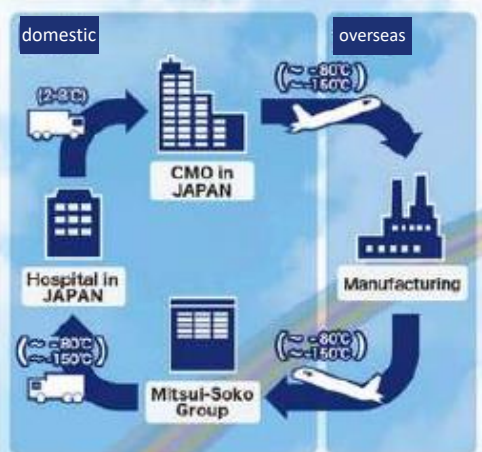
Patent No. 7304022

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MZT-M003-1.7

Regenerative medicine, Investigational drug, cell, etc. Advanced Logistics Services

Onestop Operation (GCTP facility+domestic/overseas transport)



- 1 Consigned logistics for 8 of 21 approved regenerative medicine products in Japan. (as of the end of January 2025)
 - 2 Figure Achieved high ratings from medical institutions in terms of transport quality in domestic logistics.
 - 3 We can provide one-stop service for all processes in the supply chain from Japan to overseas.
 - 4 Acquired regenerative medicine product manufacturing license (packaging, labeling and storage categories) in East and West.
- ✓ BCP measures to realize stable supply are also possible
 - ✓ Packaging and labeling work can be outsourced to us
 - ✓ Free selection of distributors and CMO for service-product separation

Service Overview

Storage

High-quality operation conforming to GCTP (multiple locations)

High-quality control at low temperature storage

[Storage in liquid nitrogen tanks, freezers, etc.]



[Environmental maintenance]
Validation, periodic inspection, temperature, etc.

[Incoming and outgoing operations in vapor phase environments, etc.]



Room temperature exposure time control, etc.

Storage facilities

Regenerative medicine logistics base

『MEDIUS-East』 @Tokyo
『MEDIUS-West』 @Kobe

- BCP measures such as quake-absorbing structure and in-house power generator
- Security management • Packaging, labeling, and inspection services

GCTP business license obtained



Collection and delivery

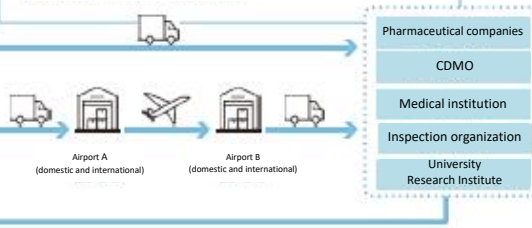
Low-temperature transport utilizing Our company's proprietary shipping containers (domestic and overseas)

- ▶ Carrier arrangement according to transportation temperature and transportation section
- ▶ Formulation of transportation procedures [SOP]
- ▶ Support for overseas transportation (including import and export operations)
- ▶ Compliance with GDP guidelines

ex.1

ex.2

Container collection



Transport container

Cryogenic transport container 『MEDI STAR EX』

- Cryogenic conditions below -150 °C maintained for 7 days
- Structure to minimize vibration
- Temperature recording/vibration recording data can be submitted

Air 1 ine-approved electronic devices are used to monitoring temperature and shock in the container.



RACTHERA Co., Ltd.

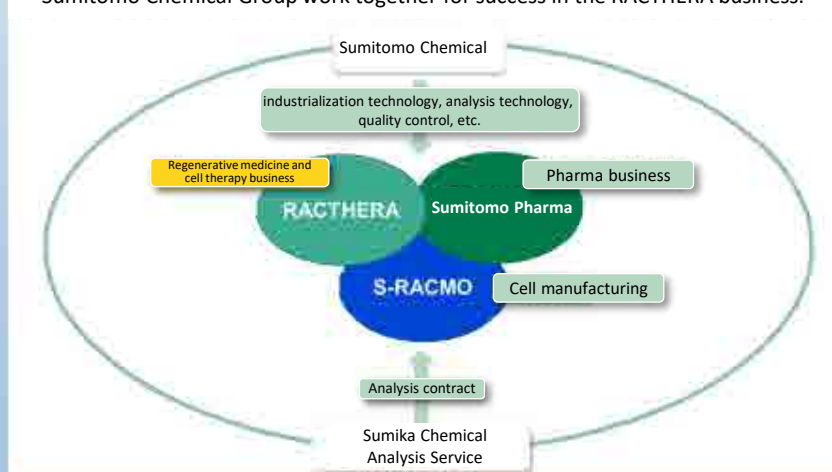
「**R**egenerative **A**nd **C**ellular **T**HERApy」

Company Name	RACTHERA, Co., Ltd.
Head Office	7-1 Nihonbashi 2-Chome, Chuo-ku, Tokyo
Research Institute	<input type="checkbox"/> Kobe Research Center: 1 -5 -2 Minatojima Minamimachi, Chuo-ku, Kobe <input type="checkbox"/> Central Research Laboratories: 33-94, Enoki-cho, Suita, Osaka
Representative	Atsushi Ikeda, Representative Director, President and CEO
Business	Research, development, manufacture, sales, and import and export of regenerative medicine and cell therapy products, cell processing products, and regenerative medicine and cell therapy-related products
Capital	¥1 million (as of the end of March, 2025)
Date of establishment	November 15, 2024 (start operations on February 1, 2025)
Shareholders	Sumitomo Chemical 66.6%, Sumitomo Pharma 33.4%

【Purpose of Establishment】

- ☐ RACTHERA is a new joint venture between Sumitomo Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo) and Sumitomo Pharma Co., Ltd. (Head Office: Chuo-ku, Osaka) and the core entity to undertake the research and development for the Sumitomo Chemical Group's regenerative medicine and cell therapy business
- ☐ To accelerate the development of regenerative medicine and cell therapy business by maximizing the Sumitomo Chemical Group's synergies, RACTHERA took over Sumitomo Pharma's regenerative medicine and cell therapy business (excluding the business related to manufacturing plant) on and launched the business on February 1, 2025
- ☐ RACTHERA is working together with Sumitomo Chemical, Sumitomo Pharma, and S-RACMO (a joint venture between Sumitomo Chemical and Sumitomo Pharma) to provide new therapeutic options to patients as soon as possible and accelerate the growth of this businesses
- ☐ By fully leveraging Sumitomo Pharma's advanced technologies and expertise cultivated through the research and development of iPS cell-derived products, as well as its proficiency in regulatory affairs and operations in the U.S., and integrating them with Sumitomo Chemical's strengths in industrialization technology, analytical technology, and quality control, Sumitomo Chemical Group aims to accelerate the early stage development and global expansion of this business. The group envisions achieving a maximum business scale of approximately 350 billion yen by the late 2030s.

Sumitomo Chemical Group work together for success in the RACTHERA business.

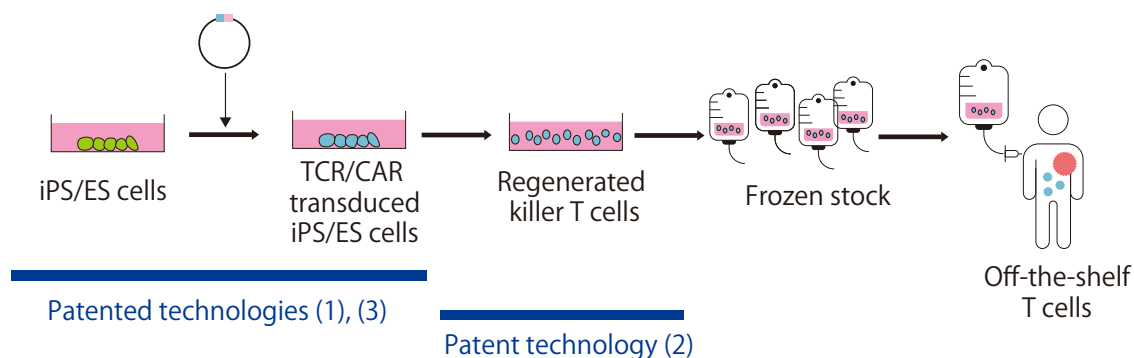


- Address: Kobe Research Center, RACTHERA Co., Ltd., 5th floor Kobe KIMEC Center Building, 1-5-2 Minatojima Minamimachi, Chuo-ku, Kobe, Hyogo 650 0047
- Contacts Ryo Yamaguchi, Katsumi Iwata
- Phone 078-306-2170 ■FAX 078-303-4040
- E-mail contact@racthera.co.jp

"We are pioneering a new era for treating diseases through the transfusion of T cell preparations!"

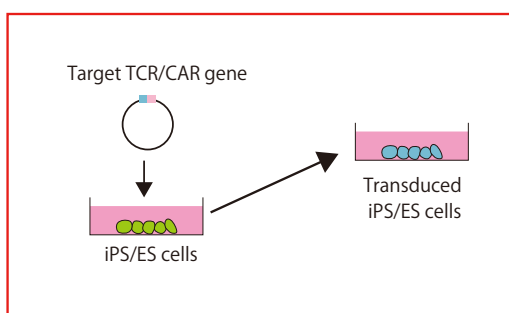
Rebirthel provides a novel treatment through super-universal T cell preparation.

"Allogeneic T cell therapy" Rebirthel develops

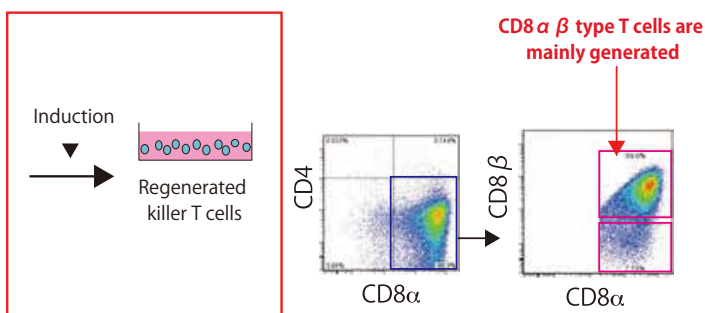


Patented technologies

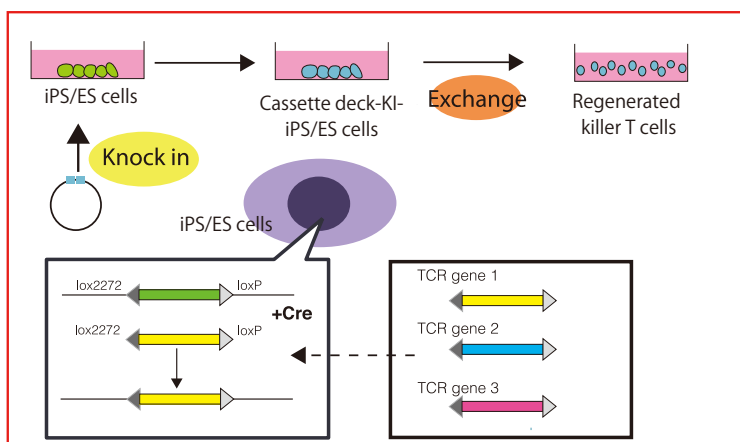
(1) TCR-iPSC method (PCT/JP2015/070623)



(2) Differentiation method (PCT/JP2017/015358)



(3) TCR cassette method (PCT/JP2019/029537)



We welcome licensing out and collaboration opportunities.

Please feel free to contact us.

info@rebirthel.com

www.rebirthel.com

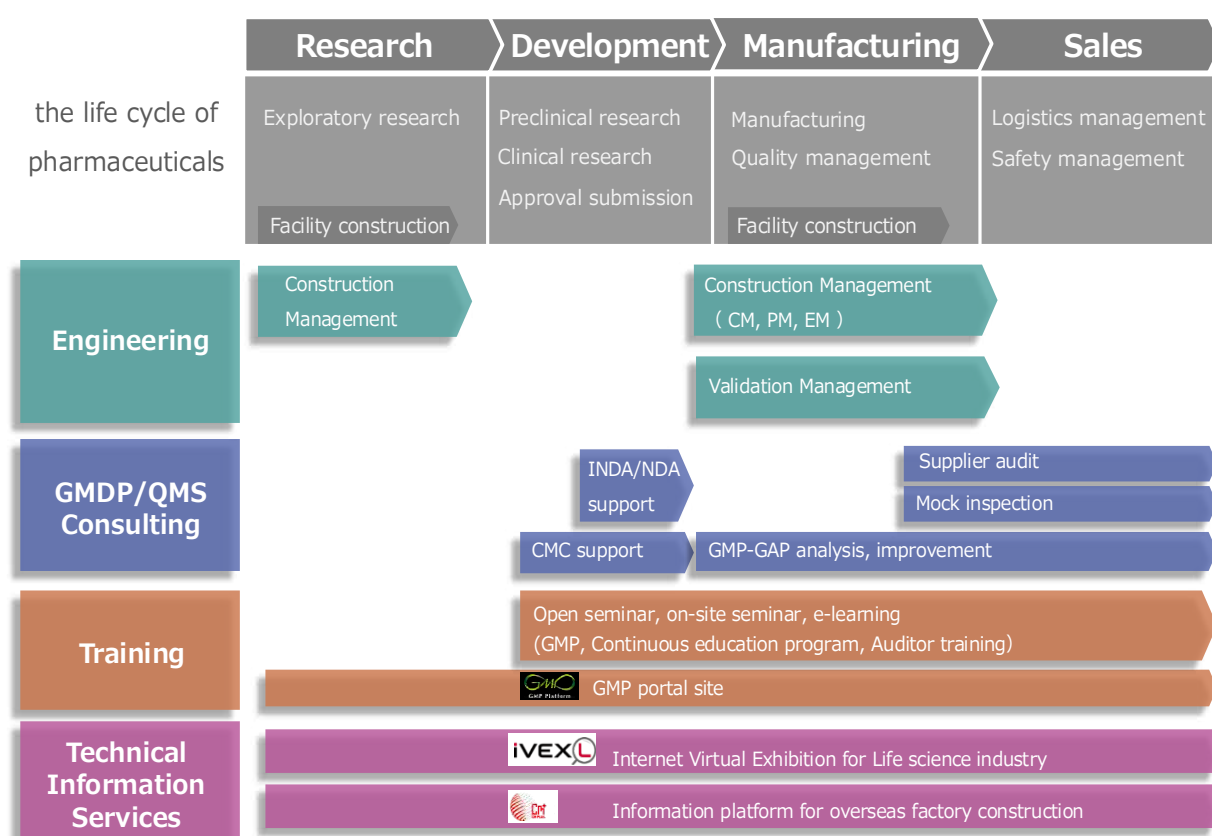


CM Plus Profile

- Consulting Maison

CM Plus provides consulting services related to the design, construction, and validation of facilities for pharmaceuticals, bioproducts, and medical devices, as well as consulting services for quality, manufacturing, and regulatory affairs. We also provide basic design, detailed design, and project management as engineering services. We will provide the specialized parts required by the customer for the project and be close to you as your brain and limbs as a "partner" in value co-creation that helps the customer realize the "creation of new value".

Service development in the life cycle of pharmaceuticals



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 CM Plus Corporation

We have a track record of 854 consulting projects and 483 engineering projects globally.

Contact: https://cm-plus.co.jp/contact_us/ HP: <https://cm-plus.co.jp/> T: 045 (514) 3336

Sumika Chemical Analysis Service, Ltd.

We are your contract analysis partner for regenerative medicine products

SCAS Sumika Chemical Analysis Service

With our high-quality data and analytical technology, we support your development of new drugs and medical treatments

- Develop test methods according to the stage of research and development
- Perform analytical tests in compliance with GMP and other regulatory requirements
- Quality evaluation of ex vivo gene therapy products and raw materials including iPS cells
- Have experience in GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice) inspections
- Propose analytical methods for various cell types
- Support the documentation for IND and NDA

Abundant Analytical Experience to comply with Regulatory Requirements

Since 2014, we've analyzed more than 1,100 products for over 40 clients

Examples	Evaluation items	Analytical Methods
	General test	Osmolality, pH, Test for extractable volume, Insoluble particulate matter test
	Content	Cell number, Cell viability, Number of cells with desired function
	Confirmation test	Appearance, Cell phenotype, Differentiation ability, Cell type, Cell authentication (STR analysis) Target cell marker, Cytokine production ability, Transgene confirmation, Residual vector
	Purity	Cell phenotype, Abnormal growth, Identification of contaminating cells (STR analysis), Non-target cell
	Process-related impurities	Process-related impurities (Serum albumin, antibiotics), Raw material vector
	Impurities with undesirable physiological activities	Physiologically active substance
	Safety	Karyotype analysis, Contamination with undifferentiated cells, Soft agar colony formation ability, Residual transgene vector, Virus, Mycoplasma, Endotoxin, Sterility test (including rapid microbiological methods)
	Potency test, Efficacy test	Protein expression, Secretion of physiologically active substances, Differentiation ability, Cell phenotype, Cell proliferation ability
	Characterization	Cell localization evaluation, Differentiation study, Storage stability evaluation, Confirmation of transgene sequence, Confirmation of vector sequence



FACS BD FACSLytic™
(2 machines)



Droplet Digital PCR
BIO-RAD QX200™



Rapid Microbial Detection System
MicroBio μ3D

SCAS Sumika Chemical Analysis Service, Ltd.
URL: <https://www.scas.co.jp/>

Contact US <https://www.scas.co.jp/contact/>



Pharmaceutical Division

Tokyo	22-5, Hongo 3-chome, Bunkyo-ku, Tokyo, 113-0033, Japan TEL. 03-5689-1217/FAX. 03-5689-1222
Osaka	6-17, Koraibashi 4-chome, Chuo-ku, Osaka, 541-0043, Japan TEL. 06-6202-1801/FAX. 06-6202-0005

Quality/
Analysis Contract

Contract Research
Organization
(Non-Clinical/Clinical)

Mediford Corporation

Safety Study Services for Regenerative Medicine

Comprehensive services in facilities compliant with **GLP** for regenerative medical products

Study type	Animals, Kits, etc.
Single-dose toxicity	<ul style="list-style-type: none"> • Mice (ICR, BALB/c, etc.) • Nude mice
Repeated-dose toxicity	<ul style="list-style-type: none"> • SCID mice • NOD-SCID mice • NOG mice • NSG mice • Rats (SD) • Nude rats
Tumorigenicity	<ul style="list-style-type: none"> • Nude mice • SCID mice • NOD-SCID mice • NOG mice • NSG mice • Nude rats
Soft agar colony formation assay	<ul style="list-style-type: none"> • CytoSelecTm 96-well cell transformation assay • Digital soft agar colony formation assay
Analysis of cell growth characteristics	Long-term culture using medium and culture method suitable for the product
Safety pharmacology	<ul style="list-style-type: none"> • Central nervous system • Respiratory system • Cardiovascular system
Others	Other study types and animal species are also available based on your requirements.

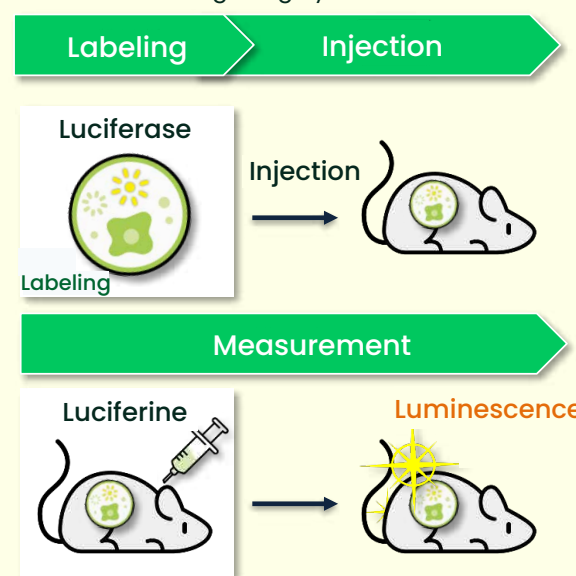
* We also offer efficacy study services.



IVIS Lumina Series III

Time-course monitoring of biodistribution in the same subject

An in vivo imaging system that captures extremely weak bioluminescence and fluorescence using a highly sensitive CCD camera



● Contact Us

Mediford Corporation



✉ medf-dds-sales@gg.mediford.com

🌐 www.mediford.com/en/

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2025.07