RDC

RESEARCH & DEVELOPMENT CENTER FOR CELL THERAPY

BRI Foundation for Biomedical Research and Innovation at Kobe

Activities of RDC

Mission

We globally demonstrate business models of medical clusters that sustainably develop Kobe Biomedical Innovation Cluster.

Foundation for Biomedical Research and Innovation at Kobe (FBRI) is positioned as the core institution of Kobe Biomedical Innovation Cluster (KBIC), one of the largest biomedical clusters in Japan.

With a focus on research, development and manufacturing of cell and gene therapy products, Research & Development Center for Cell Therapy (RDC) in FBRI is working on the development of medical industries in Kobe by collaborating with various organizations like as biological research institutions and pharmaceutical companies.

We call this ecosystem of medical industry “Kobe Cell Port City (Kobe CPC)” and we are working extensively and globally in academic societies and medical industries aiming for further expansion of this ecosystem.

Main activities

RDC are focusing on the following three categories in particular.

1. Contract manufacturing of cell and gene products

Utilizing our own Cell Processing Center (CPC), we support development of cell and gene therapy and we manufacture investigational new drugs and commercial products as a contract business.

2. Development of cloud-type cell manufacturing control system

The cell manufacturing information has not yet been digitized and most information is handwritten, therefore, the reliability is not guaranteed and integrated.
We are developing manufacturing control system that enables information to digitize information and analyze it through network.

3. Basic research on cell differentiation

We are conducting research on cell quality and biomarker identification related to the maintenance and differentiation of pluripotent stem cells such as ES/iPS cells and mesenchymal stem cells (MSC) used for cell therapy, as well as research and development of transduced T-cells.

1 Contract Manufacturing

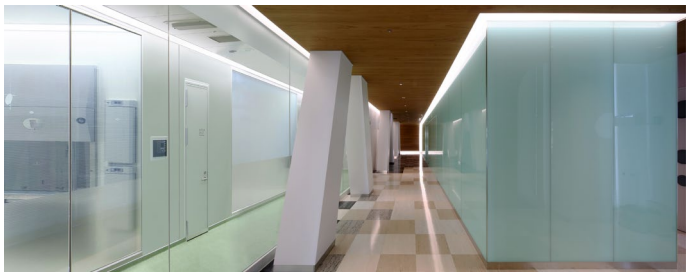
RDC has own CPCs that comply with PIC/S GMP*, and manufactures products on a contract basis under the international standardized framework.

※ The PIC/S is meant as an instrument to improve co-operation in the field of Good Manufacturing Practices (GMP) between regulatory authorities and the pharmaceutical industry.

1. Kobe Eye Center CPC

RDC has been entrusted with the manufacturing of investigational new drugs for a global pharmaceutical company at the CPCs in the Kobe Eye Center since 2018. After GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice) inspection by PMDA (Pharmaceuticals and Medical Devices Agency) in 2020, we manufacture and supply commercial products.

Kobe Eye Center



CPC floor of Kobe Eye Center

CPC

2. Kobe Center for Medical Innovation (KCMI) CPC

In March 2022, new CPCs were opened in KCMI and investigational new drugs are developed and manufactured here.

KCMI

CPC in KCMI

In KCMI CPC, the CellQualia™ Intelligent Cell Processing (ICP) System, a fully automated system jointly developed with Sinfonia Technology Co. Ltd, is installed and you can not only observe it but also use the system for demonstration of cell processing.

3. Realization of Next-Generation Cell Manufacturing System

Quality of conventional cell products is currently controlled by final inspection right before shipment. However, it is expected that the quality will be further stabilized and improved by introduction of the Quality by Design (QbD) approach that controls the quality of the manufacturing "process".

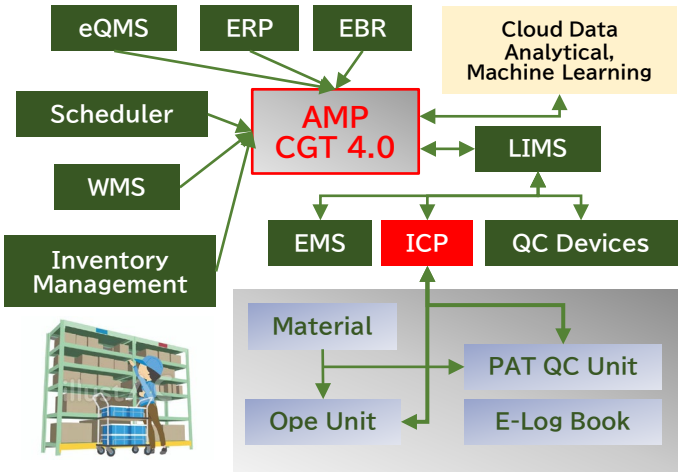
CellQualia™ ICP System

The CellQualia™ ICP System can not only automate manufacturing, but also collect and digitize data of manufacturing process, and the QbD approach is being applied to the production of ES, iPS and mesenchymal stem cells.

2 Development of Cloud-type Cell Manufacturing Control System

The most lagging behind at cell manufacturing is the spread of automation of manufacturing processes and the digitalization of manufacturing information. Most of the records such as batch records are currently handwritten on paper, and there is no cooperation or integration with other information.

In order to solve these issues, RDC is developing the new manufacturing control system that can integrate data on the cloud such as parameters for the manufacturing process, manufacturing schedule information, inventory management data, staffing plan, facility maintenance plan, data on the flow of funds for the entire factory.



3 Basic Research

1. Differentiation Potential of Pluripotent Stem Cells Correlates to the Level of CHD7. *Scientific Reports*, **8**, 241, 2018.
2. Kynurenine Signaling through the Aryl Hydrocarbon Receptor Maintains the Undifferentiated State of Human Embryonic Stem Cells. *Science Signaling*, **587**, eaaw3306, 2019.
3. Correlation Between Genetic Abnormalities in Induced Pluripotent Stem Cell-Derivatives and Abnormal Tissue Formation in Tumorigenicity Tests. *Stem Cells Translational Medicine*, **11**, 527–538, 2022.

Greetings from Head of RDC

We would like to contribute to the industrialization of the cell manufacturing through research on quality standards for cell therapy, improvement of cell manufacturing processes, support for regulatory development, and development of cell manufacturing control system. We would appreciate your continuous support on our business.

Shin Kawamata, M.D., Ph.D.
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FBRI coordinates formation of ecosystem in Kobe Biomedical Innovation Cluster

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