

FOR IMMEDIATE RELEASE

Osaka University and Hitachi Established Cell Manufacturing Simulation Engineering (Hitachi) Joint Research Chair to Promote Industrialization of Regenerative Medicine

Developing a system for the establishment of simulation technologies and industrial applications for them to stabilize and streamline cell manufacturing



From left: Susumu Kuwabata, Dean, Graduate School of Engineering, Osaka University
Masahiro Kino-oka, the director of Kino-oka Research Base for Cell Manufacturability as Innovation Research Base in Center of Excellence in Advanced Research Division of Techno Arena, Graduate School of Engineering
Hideshi Nakatsu, Vice President and Executive Officer, CEO of Water & Environment Business Unit, Hitachi, Ltd.

Tokyo and Osaka, November 30, 2023 – Osaka University (President: Shojiro Nishio, hereinafter "Osaka University") and Hitachi, Ltd. (TSE: 6501, Director, President & CEO: Keiji Kojima, hereinafter "Hitachi") today announced that they have recently established the Cell Manufacturing*¹ Simulation Engineering (Hitachi) Joint Research Chair (hereinafter the "Chair") within Osaka University's Graduate School of Engineering (Suita City, Osaka) with the goal of promoting the industrialization of regenerative medicine.

The Chair combines technology owned by Osaka University's Graduate School of Engineering for the simulation of culture processes with Hitachi's Lumada*² data analysis technology and expertise in pharmaceutical products, to establish a technology for simulating the behavior of cells used to make cell processing products and related operations and environments (e.g., culture media, reagents and containers) and also to develop a system for industrially applying the technology. By means of simulation, the Chair will identify the elements of processes that impact product quality, reduce the types and frequency of experiments using real cells, stabilize the manufacturing of cell processing products for regenerative medicine and streamline the design of the products.

*1 Cell Manufacturing: Manufacturing of cell processing products in the domain of regenerative medicine

*2 Lumada: A collective term for solutions, services and technologies based on Hitachi's advanced digital technologies for creating value from customers' data accelerating digital innovation <https://www.hitachi.com/products/it/lumada/global/en/index.html>

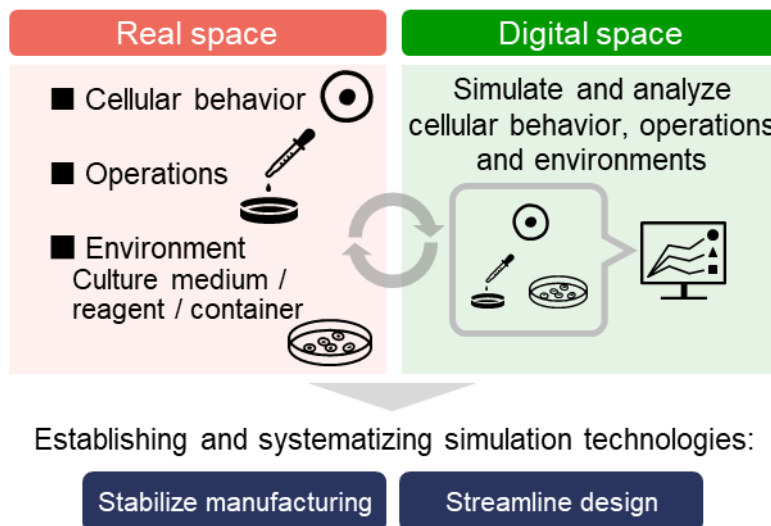
Details of the research and efforts

In pursuit of stable cell manufacturing, the Chair seeks to establish a simulation platform that considers the unevenness of cellular behavior in each process. The simulation platform models the impact of cellular behavior and other biological phenomena and related operations and environment in a digital space, and simulates and analyzes manufacturing using the group of models. Through analysis, we will seek to stabilize cell manufacturing and streamline cellular design by, for example, identifying the elements that impact the quality of cell manufacturing and providing feedback to real spaces based on forecasting from the design stage.

The Kino-oka Research Base for Cell Manufacturability^{*3} as Innovation Research Base in Center of Excellence in Advanced Research Division of Techno Arena in Osaka University's Graduate School of Engineering serves as a forum for industry-academic-government cooperation in activities such as joint research chairs and national R&D projects. Technological exchange and networking with researchers in other fields via the framework of the Research Base will pursue academic development and encouragement of industrialization in the domain of regenerative medicine, and contribution to the development of human resources rich in imagination.

^{*3} Kino-oka Research Base for Cell Manufacturability: The Research Base advocates cell manufacturability, a new concept that means possibilities of cell manufacturing (the ease of manufacturing cells) through a process of understanding and acting as a bridge between engineering perspectives and biological perspectives. Considering the concept as the foundation of learning, the research base engages in research activities.

https://www-bio.eng.osaka-u.ac.jp/ps/kotozukuri_top_en.htm



Details of the Chair's activity

Outline of the Chair

Chair title	Cell Manufacturing Simulation Engineering (Hitachi) Joint Research Chair
Objective of the research	Establish a technology for simulating the behavior, operations and environment of cells as raw materials and develop a system for industrially applying the technology
Location	CT-606, Central Terrace, Suita Campus, Osaka University
Address	2-1 Yamadaoka, Suita City, Osaka 565-0871
Duration (plan)	October 1, 2023 to September 30, 2025
Chair representative	Masahiro Kino-oka Professor at Division of Biotechnology, Graduate School of Engineering, Osaka University Akio Kani Guest associate professor (Water & Environment Business Unit, Hitachi, Ltd.)

Background behind the establishment of the Chair

It is expected that regenerative medicine will be a new method of treated intractable diseases and diseases for which no treatment is available. Promoting its industrialization requires the continuous introduction of finished goods to the market and the establishment of a stable system for manufacturing and supply. However, completely controlling a cell during cell manufacturing is difficult. Even if you perform the same operation using the same cell line in each process, the cells may behave differently. In regenerative medicine, there are challenges such as the enormous costs and time required in research, development and manufacturing. Osaka University's Graduate School of Engineering elucidates the life phenomena of a cell in the domain of biological process system engineering, and it conducts applied research related to cell manufacturing. Examples include modeling, optimization, measurement and production plans of cell manufacturing. In particular, the Kino-oka Research Base for Cell Manufacturability, adopted in 2021 as Innovation Research Base in Center of Excellence in Advanced Research Division of Techno Arena, has established an industry-academic-government think tank to develop technologies for manufacturing cells stably, safely and inexpensively and also develop regulations, international standards and human resources at the same time. In this way, the Center seeks to implement cell manufacturing in the community. For many years, the Hitachi Group has offered Lumada's data analysis technology, production equipment and devices including culture equipment for use in the pharmaceutical domain and Operational Technology and IT systems such as production and quality control systems. We are also accelerating efforts in the domain of regenerative medicine. For example, Hitachi Plant Services Co., Ltd. established the Hitachi Plant Services Research Alliance Laboratories within Osaka University's Graduate School of Engineering in 2018 and it is also involved in the activities of Nakanoshima Qross which is scheduled to open in 2024.

Amid these efforts, we are developing a system for establishing and industrially applying a cell manufacturing simulation technology using the simulation technology owned by Osaka University's Graduate School of Engineering to break down the phenomena in the culture process and reproduce them in a computer and Hitachi's technologies and expertise that is has cultivated in the pharmaceutical domain.

About Osaka University

Osaka University was founded in 1931 as one of the seven imperial universities of Japan and is now one of Japan's leading comprehensive universities with a broad disciplinary spectrum. This strength is coupled with a singular drive for innovation that extends throughout the scientific process, from fundamental research to the creation of applied technology with positive economic impacts. Its commitment to innovation has been recognized in Japan and around the world, being named Japan's most innovative university in 2015 (Reuters 2015 Top 100) and one of the most innovative institutions in the world in 2017 (Innovative Universities and the Nature Index Innovation 2017). Now, Osaka University is leveraging its role as a Designated National University Corporation selected by the Ministry of Education, Culture, Sports, Science and Technology to contribute to innovation for human welfare, sustainable development of society, and social transformation.

For more information, please visit the Osaka University website (<https://www.osaka-u.ac.jp/en>).

About Hitachi, Ltd.

Hitachi drives Social Innovation Business, creating a sustainable society through the use of data and technology. We solve customers' and society's challenges with Lumada solutions leveraging IT, OT (Operational Technology) and products. Hitachi operates under the business structure of “Digital Systems & Services” - supporting our customers' digital transformation; “Green Energy & Mobility” - contributing to a decarbonized society through energy and railway systems, and “Connective Industries” - connecting products through digital technology to provide solutions in various industries. Driven by Digital, Green, and Innovation, we aim for growth through co-creation with our customers. The company's consolidated revenues for fiscal year 2022 (ended March 31, 2023) totaled 10,881.1 billion yen, with 696 consolidated subsidiaries and approximately 320,000 employees worldwide. For more information on Hitachi, please visit the company's website at <https://www.hitachi.com>.

Business Contact:

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Water & Environment Business Unit, Hitachi, Ltd.

https://www8.hitachi.co.jp/inquiry/hitachi-ltd/water/en/control_system/form.jsp

Information contained in this news release is current as of the date of the press announcement, but may be subject to change without prior notice.
