Stem Cell Engineering for Regenerative Medicine: Bioprocessing Innovations and Future Directions

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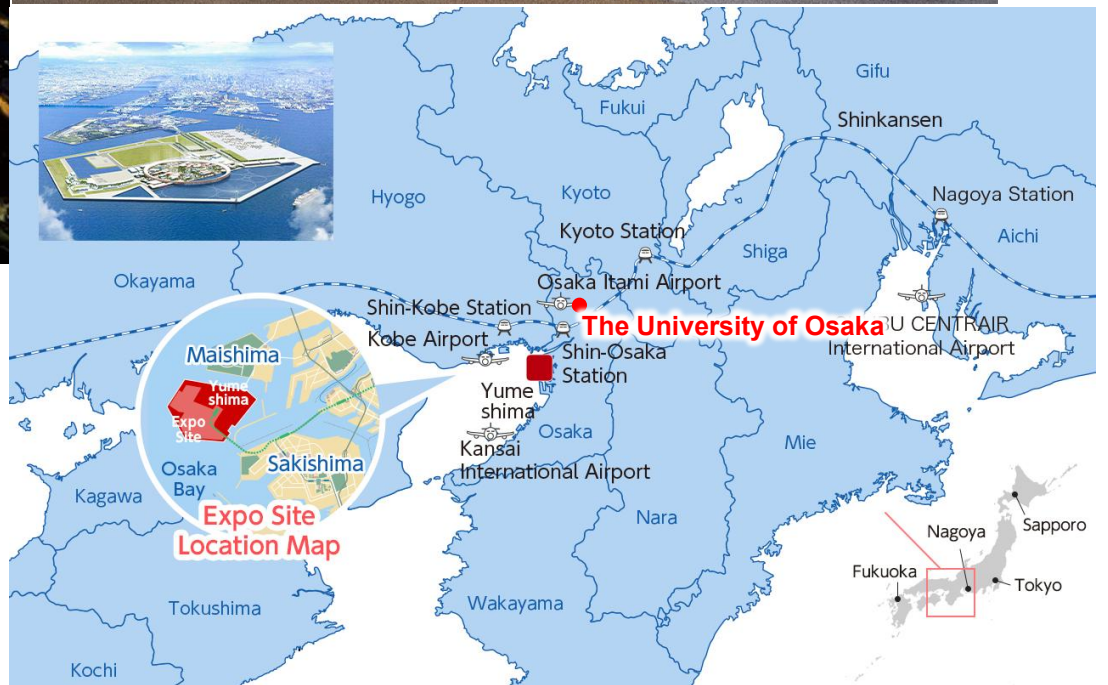
Organized by ProSTEM BRIN

"Future Directions and Opportunities for Clinical Application and the Health Industry in Stem Cell Innovation"

I come from Osaka, Japan

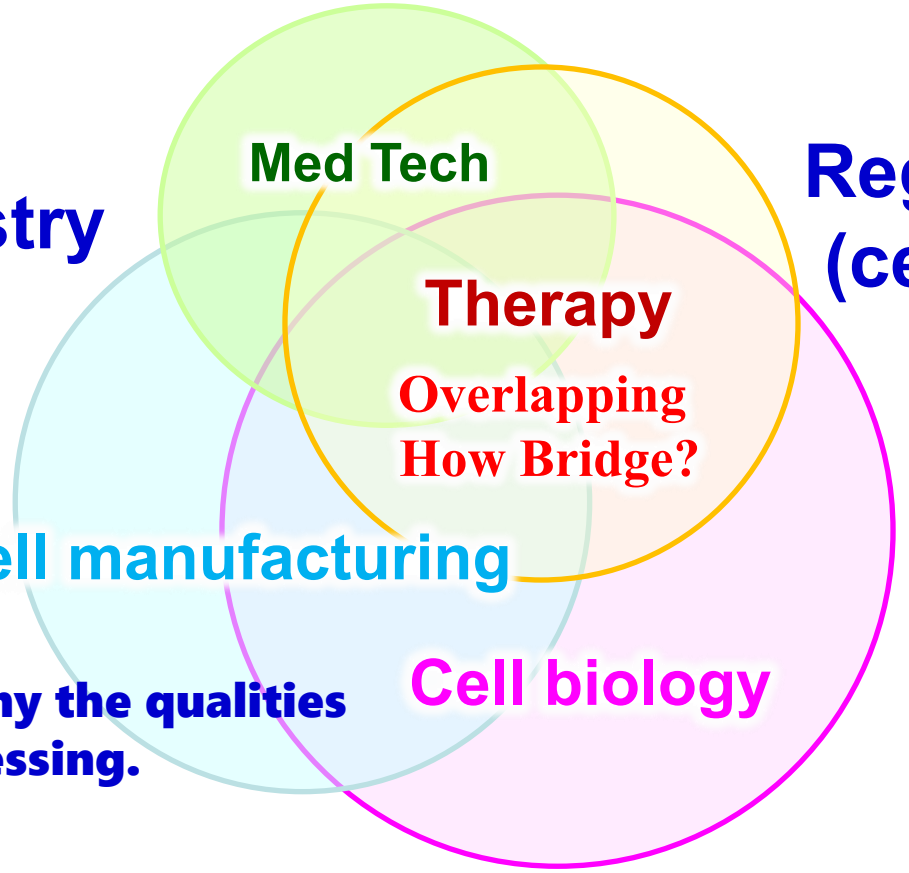
https://www.expo2025.or.jp/en/overview/

Designing Future Society for Our Lives



We want to provide good therapy to the patients.

We don't know the cells as well as EVs.



Tech. Industry

Regenerative medicine (cell therapy)

Academic

Engineering, Informatics
Biology, Pharmacy, Medicine
Management, Law

We don't know the reason why the qualities are changed during cell processing.

A new medicine and industry that needs academic support!

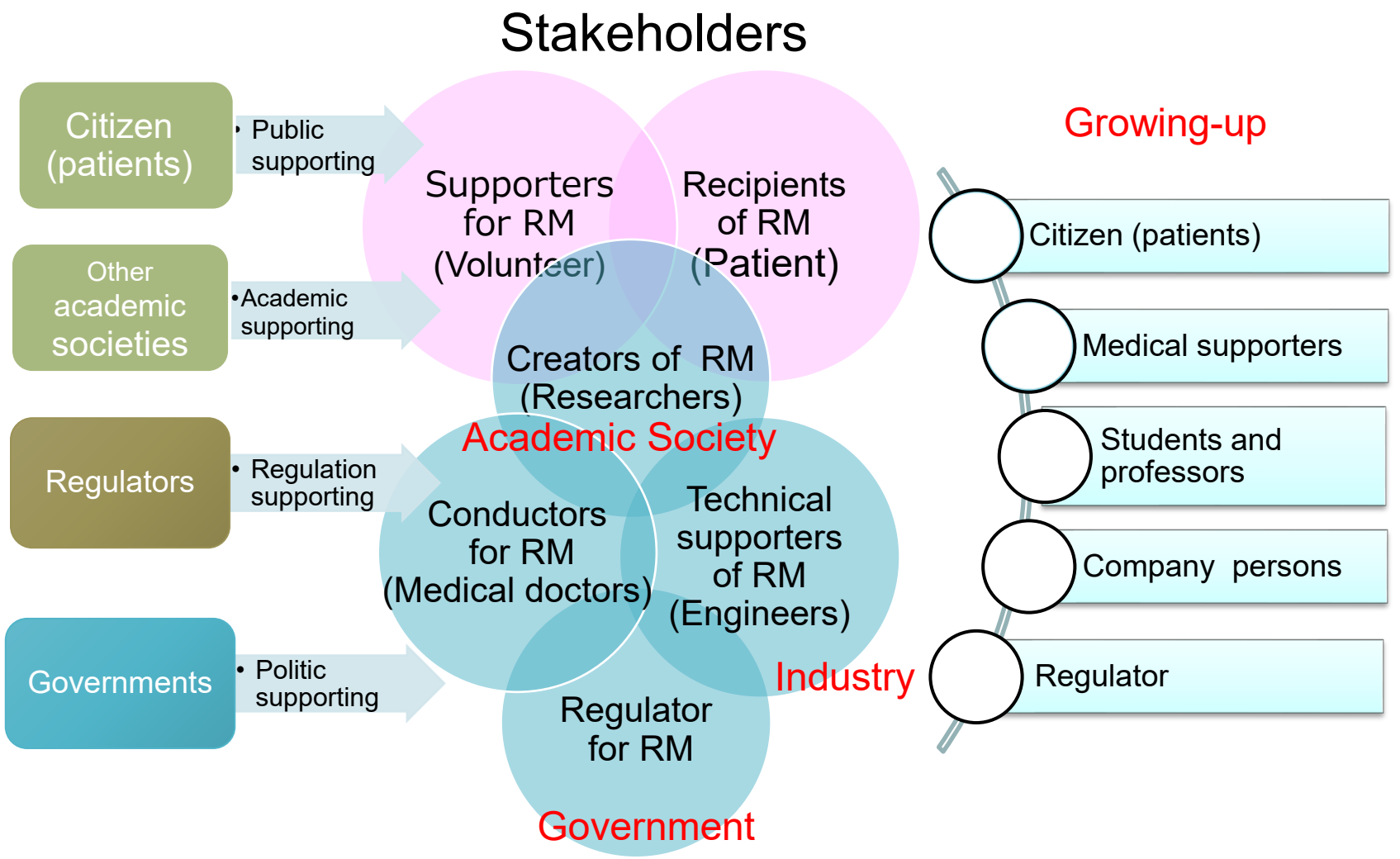
Companies, universities and government will go bankrupt if they do not provide profitable services.

Cell Manufacturability

Regenerative Medicine in Japan

Academic society

ca. 10 years history



JSRM

Japanese Society for Regenerative Medicine (JSRM)
supports the good communication with all stakeholders

Cell Manufacturability

Activities in Japanese Society for Regenerative Medicine(JSRM)

Academic Society

National Consortium for Regenerative Medicine

Since Dec. 2016

JSRM

Courtesy of JSRM

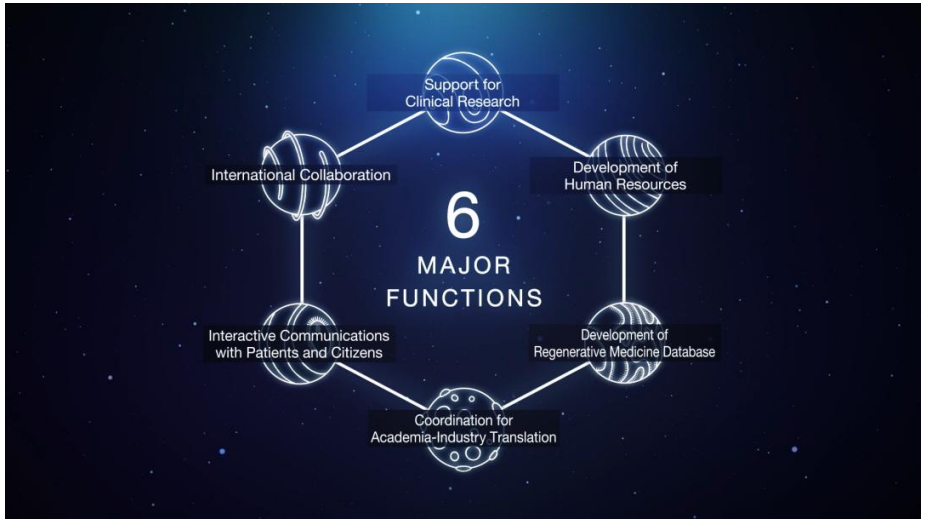
National
Consortium
for Regenerative
Medicine

再生医療
ナショナル
コンソーシアム

ncrm

The Japanese Society for
Regenerative Medicine

日本再生
医療学会



Human resources development

https://www.youtube.com/watch?v=fHGrgUyrs9g&t=1s

Cell Manufacturability

Activities in Japanese Society for Regenerative Medicine(JSRM)

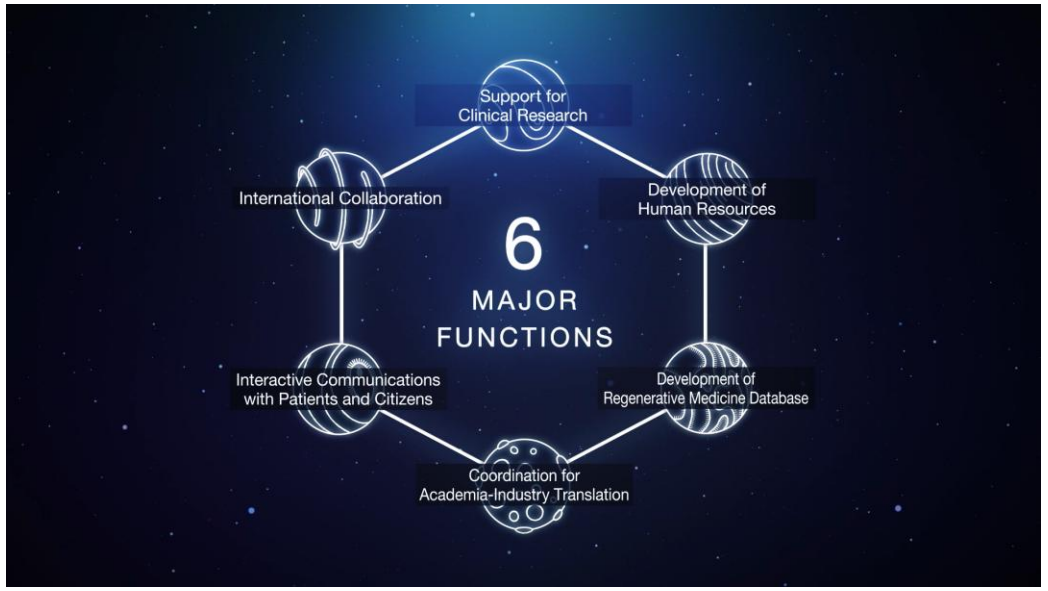
Academic Society

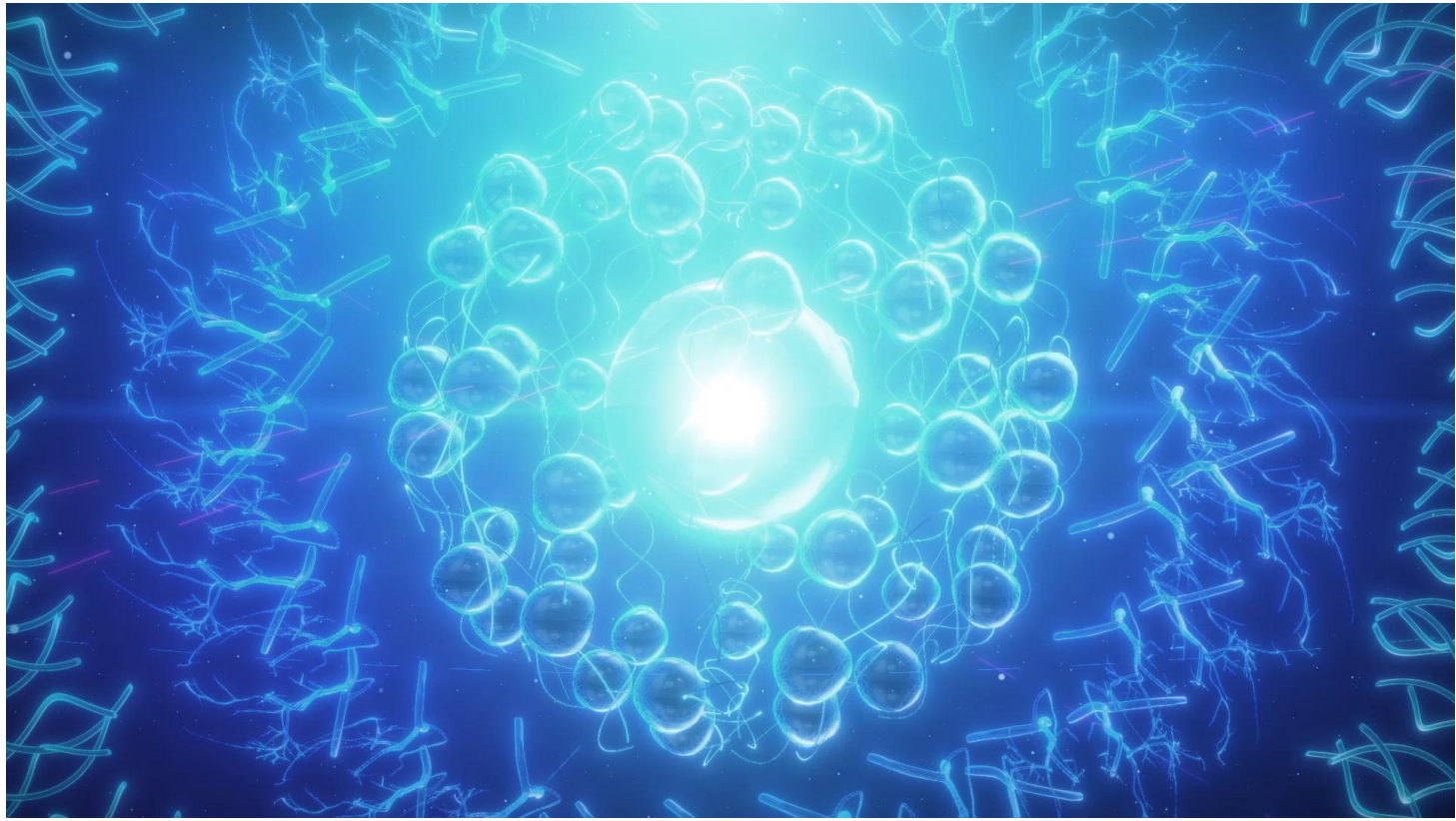
National Consortium for Regenerative Medicine

Since Dec. 2016

JSRM

Courtesy of JSRM





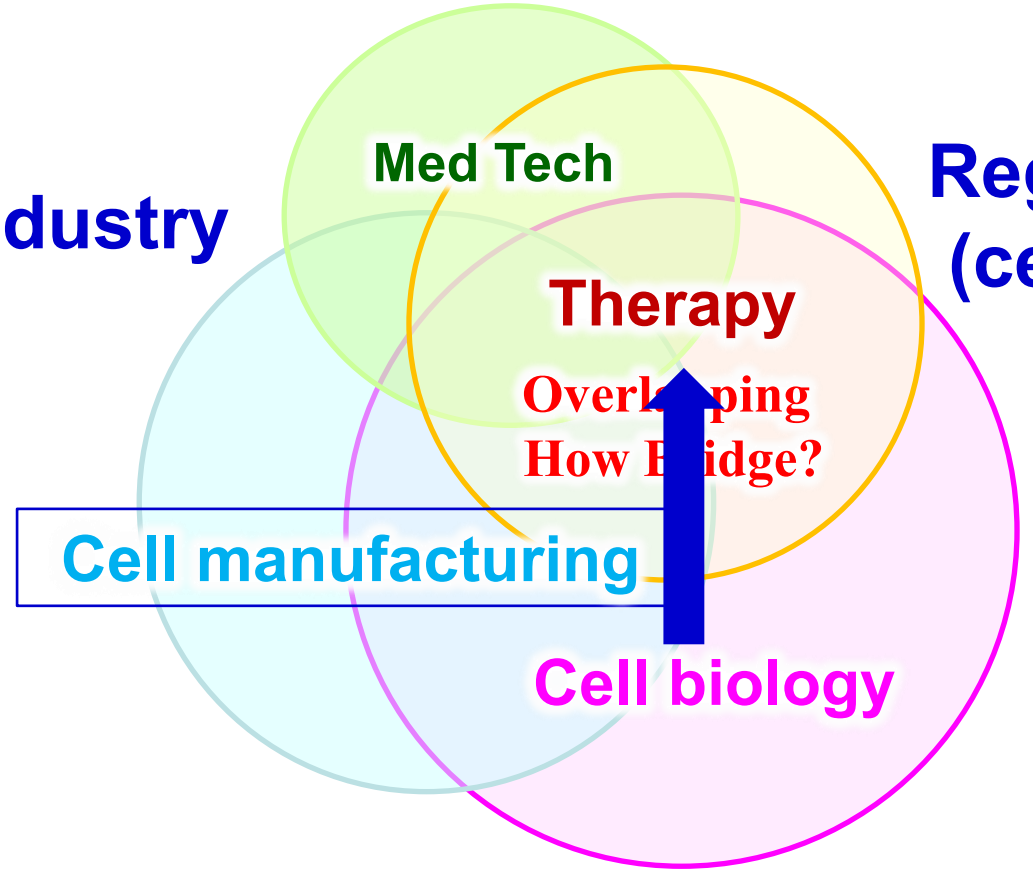
https://www.youtube.com/watch?v=fHGrgUyrs9g&t=1s

6 major functions (modules)

1. Support for Clinical Research
2. Development of Human Resources
3. Development of Regenerative Medicine Database
4. Coordination for Academia-Industry Translation
5. Interactive Communications with Patients and Citizens
6. International Collaboration

Cell Manufacturability

Activity in Research Base of Cell manufacturability in The University of Osaka



Tech. Industry

Regenerative medicine (cell therapy)

Overlapping
How Bridge?

Our standpoint

Cell manufacturing

A new medicine and industry that needs academic support!

Companies, universities and government will go bankrupt if they do not provide profitable services.

Academic

Engineering, Informatics　Biology, Pharmacy, Medicine
Management, Law

Activity in Research Base of Cell manufacturability in The University of Osaka

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

Importance of development of the consortium
to make deep and valuable discussion of technology and regulation for cell manufacturing
to develop of human resources with a sense of sophistication.

Research Base for Cell Manufacturability
TechnoArena, Graduate School of Engineering
The University of Osaka


Director
Prof. Kino-oka


Deputy director
Lec. Mizutani


Dr. Fukumori


Mr. Uno

Core Lab. members

Origin Lab.
BioProcess Systems Engineering lab.


Prof. Kino-oka


Assoc. Prof. Kim


Assist. Prof. Yamamoto

Joint Research Labs.

RORZE Lifescience Joint Research Chair for Cell Culture Engineering


Assoc. Prof. Hata

Joint Research Chair on Design for Advanced Medical System


Assoc. Prof. Saito

Cell Manufacturing Simulation Engineering (Hitachi) Joint Research Laboratory


Assoc. Prof. Kani

Joint Research Laboratory (Iwatani) for Cell Storage & Transport Technology


Assoc. Prof. Nakamura

Cell Manufacturing Design (CET) Joint Research Laboratory


Assoc. Prof. Maekawa

Joint Research Laboratory (Fujimori Kogyo) for Social Implementation of Bio-Manufacturing


Assoc. Prof. Muraoka

Activity in Research Base of Cell manufacturability in The University of Osaka

Since April 2016

Former name ;**Kotozukuri Consortium for Cell Manufacturability**

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

Cell Manufacturability

Expert Platform for start-up

Promoting the formation of an industrial base
through a consortium of multiple laboratories and organizations

Core members in companies' laboratories

大阪大学 × 遊谷工業 未来医療システムデザイン（遊谷工業）共同研究講座

RORZE Lifescience × 大阪大学 ローツェライフサイエンス細胞培養工学共同研究講座

大阪大学 × Iwatani 細胞保管・輸送テクノロジー（岩谷産業）共同研究講座

大阪大学 × CET 細胞製造デザイン学(CET)共同研究講座

大阪大学 HITACHI 細胞製造シミュレーション工学（日立）共同研究講座

大阪大学 ZACROS バイオものづくり社会実装（ZACROS）共同研究講座

Systematization

Cell manufacturability

Co-creation with the experts

Create new industries in fields of regenerative medicine, cell therapy, biopharmacy and food etc.

Technological development ‘Mono-zukuri’

Collaboration with companies and universities

Academic background

Biochemical engineering
Cell manufacturability
Aseptic processing

Research Base for Cell Manufacturability

Grad. Sch. Eng. Osaka University

Collaboration with government, academic societies, and industrial association

Collaboration with universities and academic societies

Rule development ‘Rule-zukuri’

Human resource development ‘Hito-zukuri’

ISO JSRM pmda

Regulation / Standardization

Customer collaboration
Social implementation
Globalization

Nakanoshima Qross 未来医療国際拠点 MEI JSRM Tokyo University of Science EARTH Environmental Service

Expert education and training
Instructions

https://www.youtube.com/watch?v=w2tteV7oxo8

Collaboration for Human Resources Development in The University of Osaka

Global Center for Medical Engineering and Informatics (MEI), Osaka University

MEI

with other companies

ex. **Earth Environmental Service Co.**
T-CUBE (training center), Osaka

EARTH Environmental Service

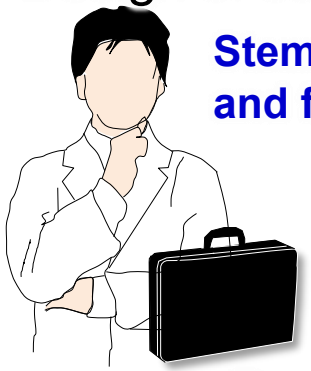
Training center for aseptic processing and hygiene management

Activity in Research Base of Cell manufacturability in The University of Osaka

Core technologies

Lec. Mizutani

Design of cell nurturing



Stem cell expansion and fate control

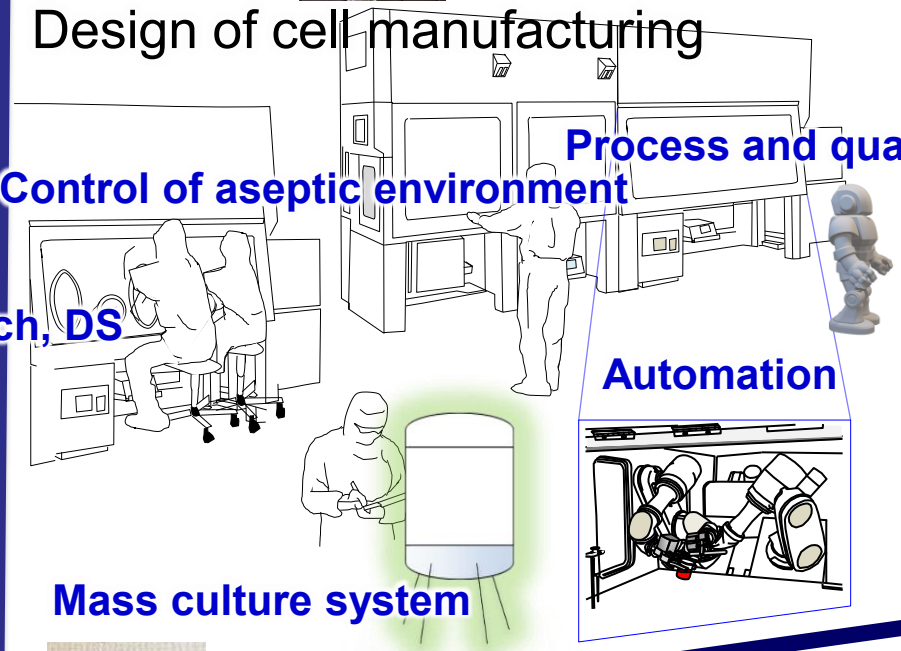
QbD approach, DS

Design of CQAs

Cell potency assay

Assoc. Prof. Kim

Design of cell manufacturing



Control of aseptic environment

Process and quality stability

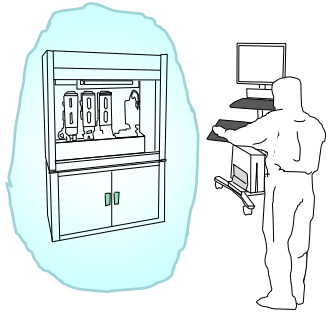
Automation

Mass culture system

Assist. Prof. Yamamoto

Design of treatment in home

Hospital

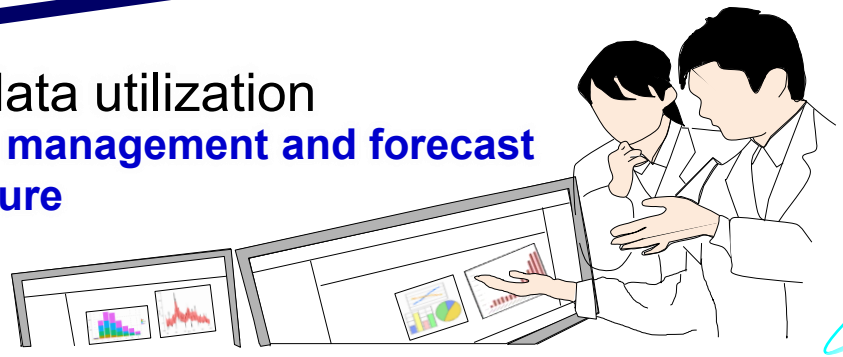


Design of data utilization

Manufacturing management and forecast

Prediction of cure

Visiting Assist. Prof. Sasaki



Cell Manufacturability

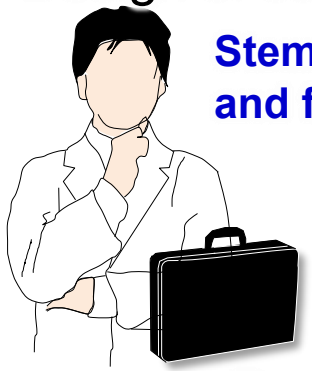
Activity in Research Base of Cell manufacturability in The University of Osaka

Core technologies

1. Platform by experts

Design of cell nurturing

Stem cell expansion and fate control



QbD approach, DS

Design of CQAs

Cell potency assay

2. Comparability of product quality

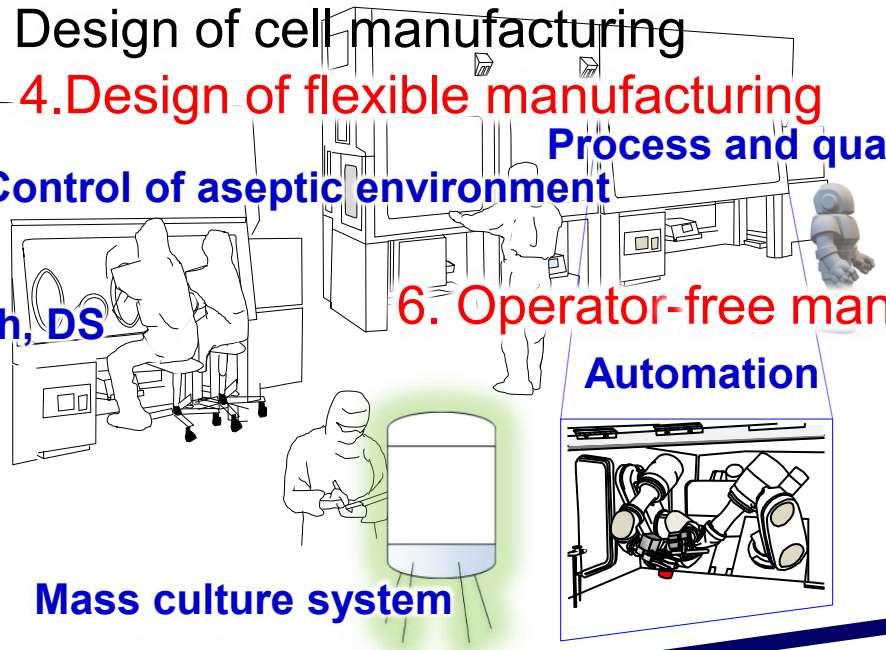
3. Cell distribution

Design of cell manufacturing

4.Design of flexible manufacturing

Process and quality stability

Control of aseptic environment



6. Operator-free manufacturing

Automation

Mass culture system

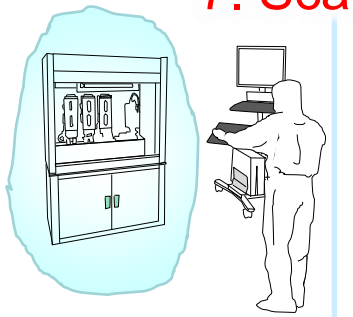
5. Scale-up

Design of treatment in home

8. Robotic rehabilitation

Hospital

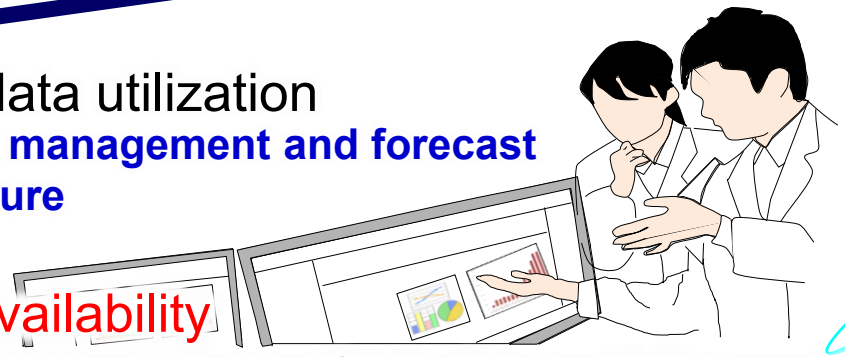
7. Scale-out



Design of data utilization

Manufacturing management and forecast

Prediction of cure



9. Data Availability for cell source, manufacturing and therapy

10. Contribution toward future therapy (exosome etc.)

Activity in Research Base of Cell manufacturability in The University of Osaka

大阪大学 THE UNIVERSITY OF OSAKA 澁谷工業
未来医療システムデザイン
（澁谷工業）共同研究講座

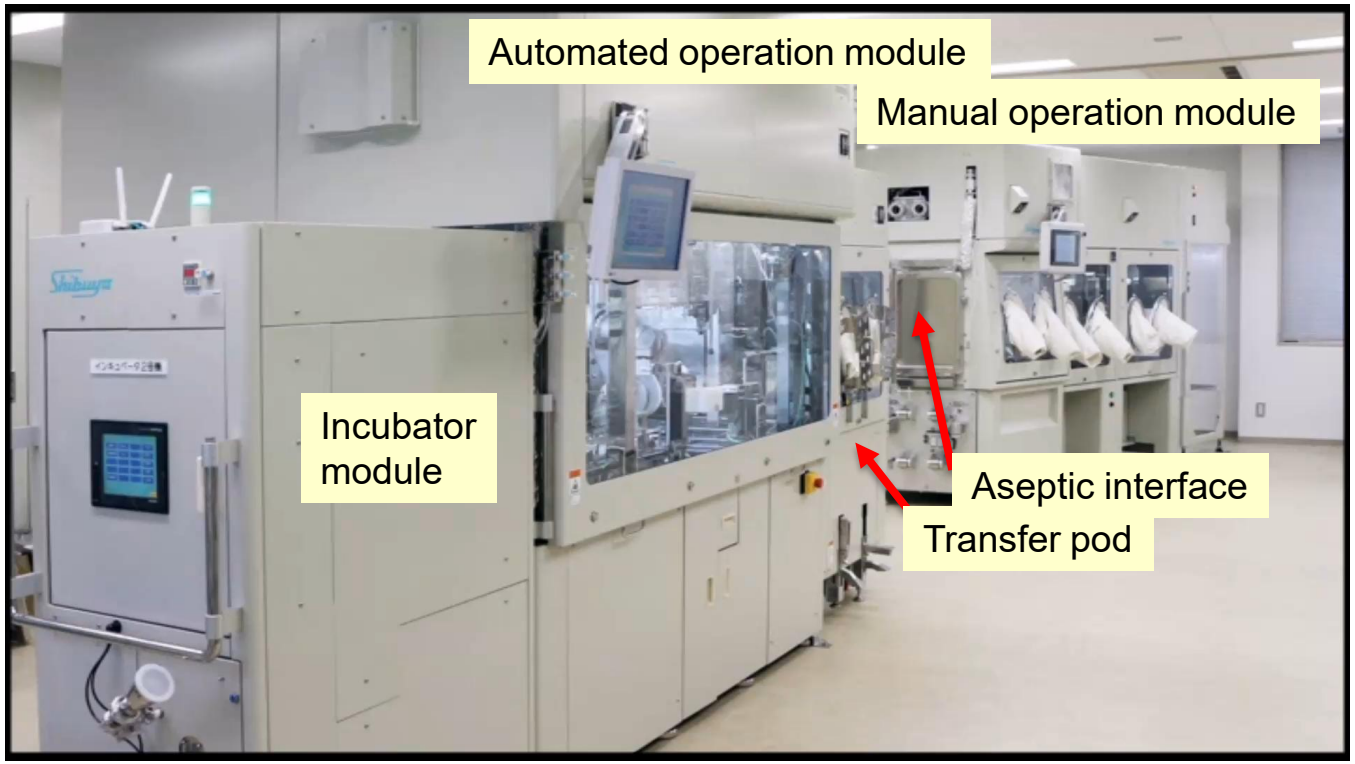
Core technologies

Isolator system for cell manufacturing

Automation

Saving-cost
Stability of process

Application: MSC culture
iPSC culture
RPE culture



flexible Modular Platform (fMP) for parallel processing of multi-purposes under GMP (GCTP)

Multi-purpose automation systems

Compatible modules

Independent-operated modules

Interface technology (processes, facilities, devices, vessel, information, person)

Less operators (3-4 persons) with minimum number of expert

Non-stop manufacturing without interruptions due to inspections

Cell Manufacturability

Research Base for Cell Manufacturability

TechnoArena, Graduate School of Engineering
The University of Osaka

Core technologies


Room for scale-up technology


Room for automation technology

Scaling system

Lab. scale

Manual operation

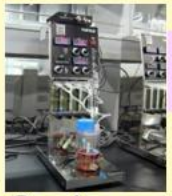
Mass production

Manufacturing system development

Mechanization

Development of super-mass culture technologies

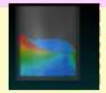

Scale-down (0.005L)


Scale-up (>0.1L)

Large (>1L)


Medium change in closed system

Super mass (> 10L)


Fluid analysis


10-L culture bioreactor


Scale-out (processing in disposable bag)

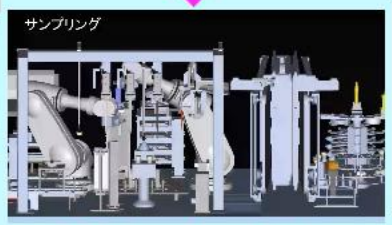

Freezing and storage system

Development of Intelligent system (automation and prediction) for aseptic processing

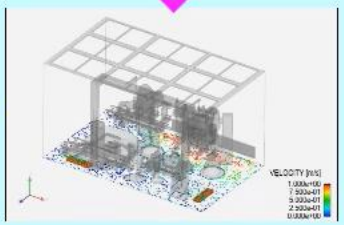
Automation system

Cold chain

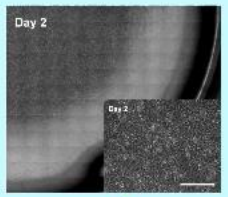
Hygiene management system



Motion simulation

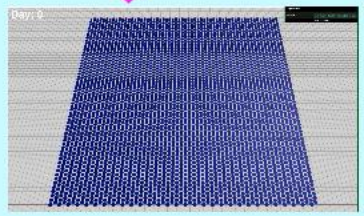

Air flow simulation

Process & Quality management



Automation & Data acquisition & Prediction system

Digital recording tool



Cell culture simulation


Process simulator

Digital Twining

Smart manufacturing system

Automated Cell Manufacturing System

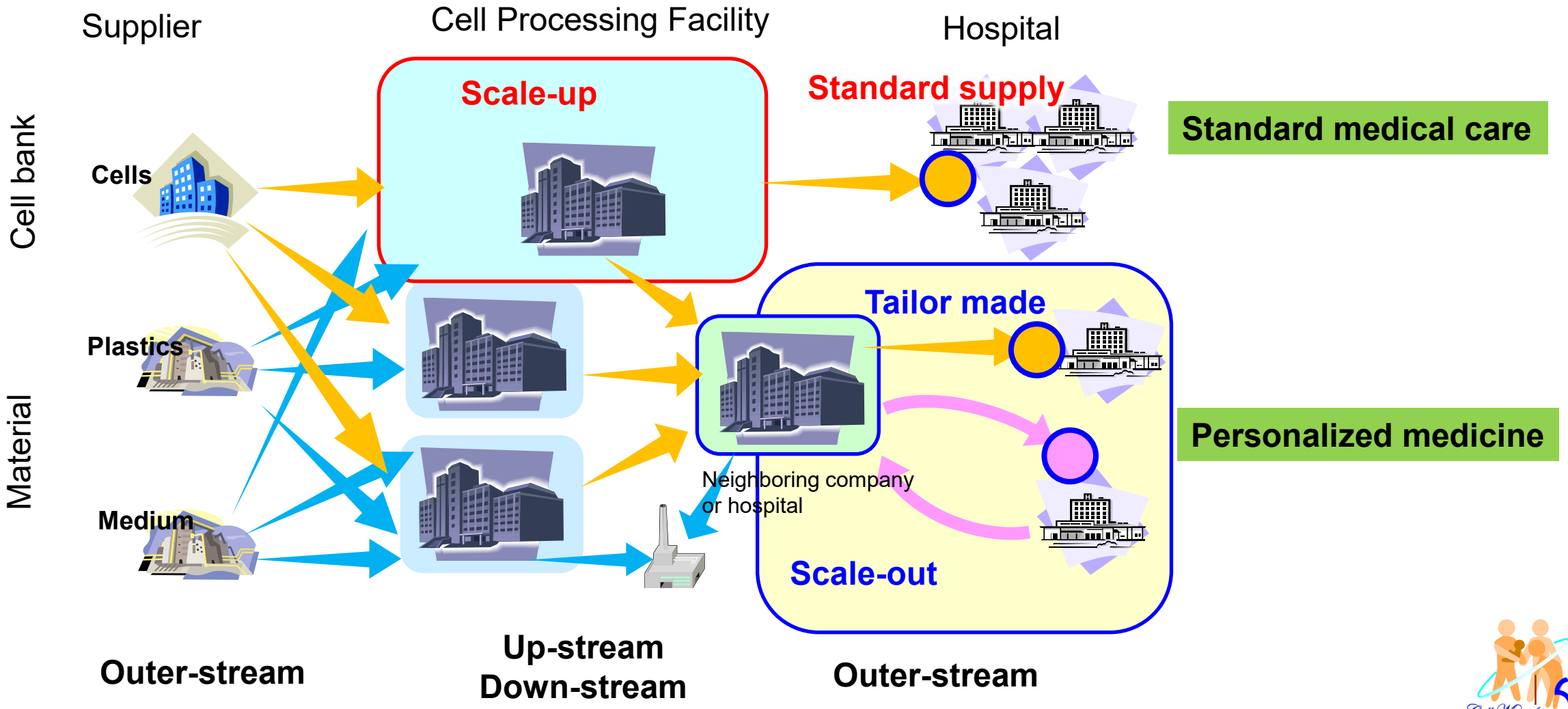
Ecosystem for future medicine

Social implementation of regenerative medicine and cell therapy

Diversity of targeted system construction and cell manufacturing

Allogenic cells → Autologous cells → Materials and Wastes

Cell processing in Hospital
(cell thawing, washing et al..)



Cell Manufacturability

Design of digital twin for cell manufacturing

Digital Twining in Cell Manufacturing

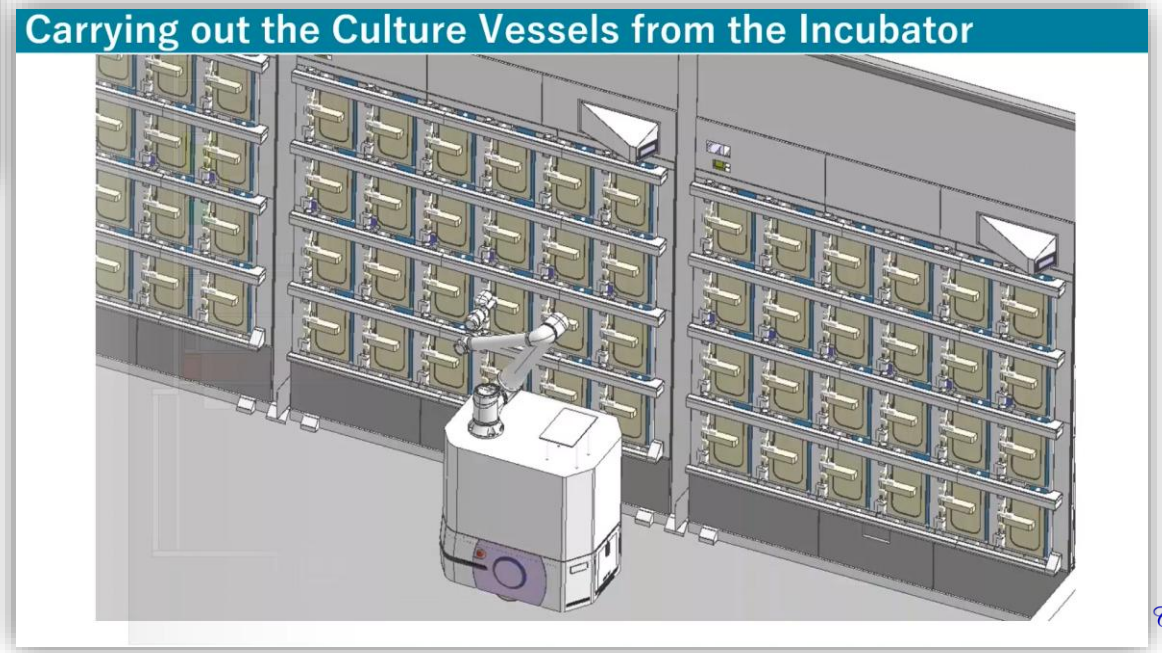
大阪大学 THE UNIVERSITY OF OSAKA 渋谷工業
未来医療システムデザイン
（渋谷工業）共同研究講座

Future prospective: Operator-free cell manufacturing

Automated Cell Manufacturing System

World Leading Technology Shibuya

Mechanization with Robotics
and
Simulation with AI



Cell Manufacturability

Ecosystem for future medicine

Social implementation of regenerative medicine and cell therapy

International Center for Future Medical Care in Osaka

Open in 29th Jun, 2024 (Nakanoshima area)

Nakanoshima Qross
未来医療国際拠点

Nakanoshima Museum of Art

Osaka Univ. (Nakanoshima Campus)

Technology/human/information resources

Think tank (good meddle/OSEKKAI team)

Research Base for Cell Manufacturability

Data bases

Private data bank

Public data bank

Company Manufacturing data

Company material data

Medical Chain

Medical network

Care/Therapy Rehabilitation

Cycling

Seed Chain Universities

Supply Chain

Medical devise/Medicine companies

Cell Manu.

Drug

Devise

Tools

Value Chain

Cells

Suppliers

Facility/devise

Raw materials (medium)

Plastic vessels

Thank you!

Acknowledgement

“Research Base for Cell Manufacturability”
Graduate School of Engineering, Osaka University(2021.4 – 2026.3)

“National Consortium for Regenerative Medicine”
(JP21bk0304001) by Japan Agency for Medical Research and Development (AMED) (2016.12 – 2026.3)

“Establishment of QbD-based control strategy and advanced core ecosystem in cell manufacturing”
(JP20be0704001) by Japan Agency for Medical Research and Development (AMED) (2020.11 – 2025.3)

Leaflet of our research base

Policy and future activities of our research base

Core Members
in Research Base for Cell Manufacturability