Business Briefing on CDMO* business for bio-antibody drugs

March 2024

SIIX Corporation

*CDMO: Contract Manufacturing and Development Organization

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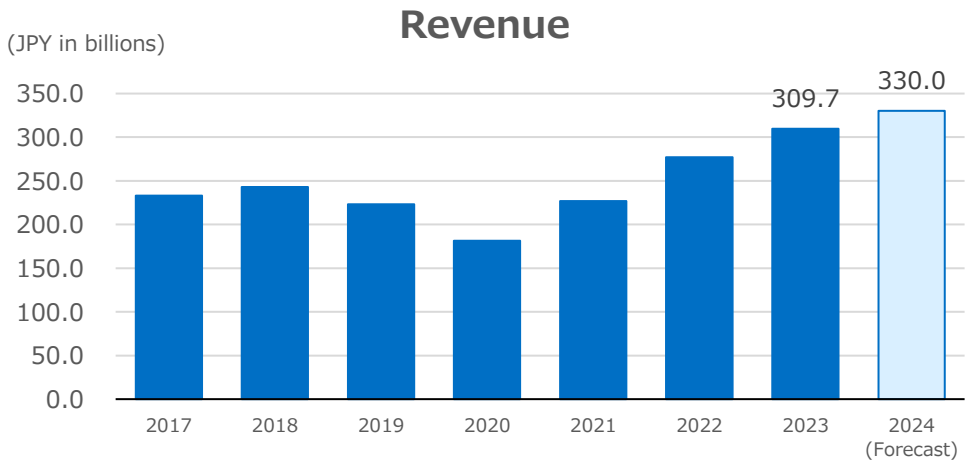
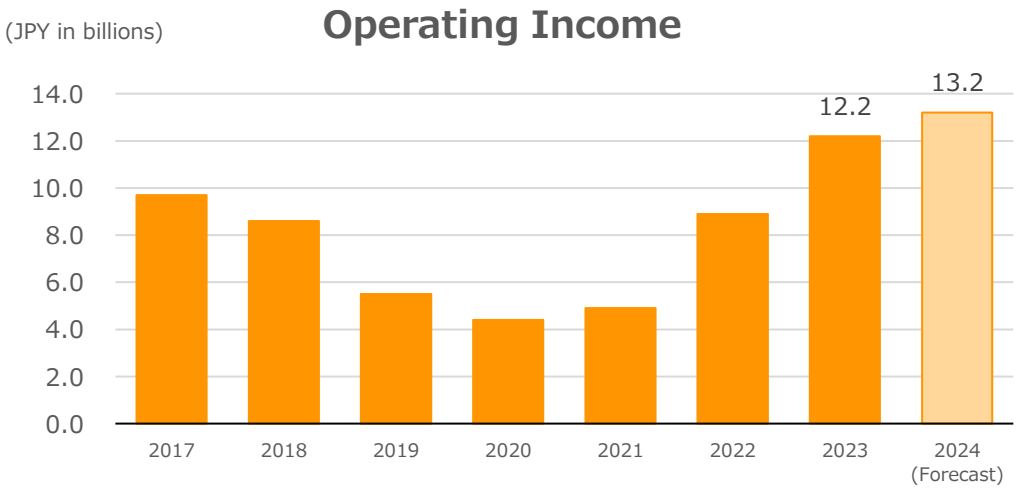
- Corporate Profile of SIIX Corporation
- Corporate Profile of RENZOKU Biologics Inc.
- Entry into the CDMO business for antibody drugs
- Introduction of CEO of Renzoku Biologics Inc.

Corporate Profile

Name	SIIX Corporation
Type of Industry	Trading of Electric Components & PCBA, EMS
Establishment	July 1, 1992
Capital	JPY 2,144 million
Location	Osaka Headquarters（Chuo-ku Osaka, Japan） Tokyo Headquarters（Chiyoda-ku Tokyo, Japan） Nagoya Sales Dep.（Nagoya, Aichi, Japan）
Listed Market	Prime Market, Tokyo Stock Exchange（Ticker Code : 7613）
# of Employees	Consolidated 11,052, Non-consolidated 214（as of DEC 2023）
Network	Overseas 22（10 factories, 12 Offices） Domestic 2（Headquarters, 1 Factory）(as od DEC 2023)
認証取得	ISO9001, ISO14001, ISO27001, IATF16949, ISO13485

Major Shareholders		
	Sakata Inx Corp.	21.45%
	Japan Master Trust	8.82%
	SIIX Corp.	6.60%
	Forty-Six	4.37%
	Resona Holdings, Inc.	4.31%
	Sumitomo Mitsui Banking Corporation	4.29%





Corporate Profile of Renzoku Biologics

Company Name	**Renzoku Biologics Inc.**
Location	Marunouchi Trust Tower 20F, 1-8-3, Marunouchi, Chiyoda-ku, Tokyo, Japan
Representative	Hitoshi Kuboniwa, PhD, CEO
Establishment	August 22, 2023
Capital	JPY 1,195 million
Shareholding	SIIX Corp. 96%
Fiscal Period	December
Main Business	Contract development and manufacturing of antibody drugs, etc.

SIIX We care.

Entry into the CDMO business for antibody drugs

Background

We organize customers needs around the world to create business as

Global Business Organizer

- In researching the healthcare-related market, we noticed that there is a strong **unmet need** in the biopharmaceutical field.
- In the pharmaceutical industry, as in the electronics industry, there is a **horizontal division of labor**.
- **High affinity of business model**

Our Target

- "EMS for pharmaceuticals" = Entry into CDMO business (contract manufacturing and development business)
- Aiming for social implementation of fully continuous production technology with excellent production scale variability and flexible response to small- and medium-volume, high-mix production.
- Maximize synergies with the antibody drug field by leveraging our expertise in operations management and global expansion cultivated as an EMS

Operations Management: DX/ICT-enabled data, quantification, visualization, remoteness, traceability, etc. Expertise in automation and labor saving

SIIX We care.

Introduction of CEO of Renzoku Biologics Inc.

Chief Executive Officer

Hitoshi Kuboniwa (PhD)

Former Senior Executive Officer, Pharmaceuticals representative, Managing Executive Officer, General Manager of Pharmaceuticals Division of Chugai Pharmaceutical Co., Ltd.

D. in Polymer Engineering, Tokyo Institute of Technology
More than 40 years of experience in R&D, business development, biopharmaceutical manufacturing and supply chain management in major pharmaceutical company

Chair, Steering Committee, Japan Bioindustry Association (JBA)
Chairman, JBA Drug Discovery Modality Infrastructure Research Group

Renzoku Biologics

Renzoku Biologics

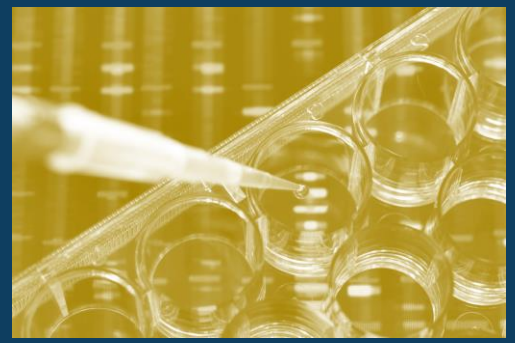
A Centre of Excellence for Advanced Biomanufacturing

March 2024

Presentation Summary

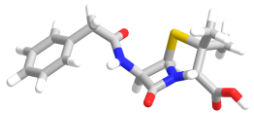
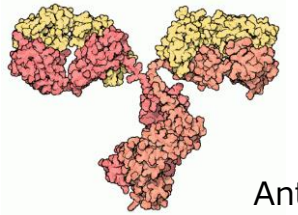
1. About Biopharmaceuticals
2. Biopharmaceutical Manufacturing and CDMOs
3. About Renzoku Biologics
4. CDMO Market Entry Strategy
5. Collaboration with SIIX Corp.

Renzoku Biologics


1. About Biopharmaceuticals

Small molecule drugs & Biopharmaceuticals

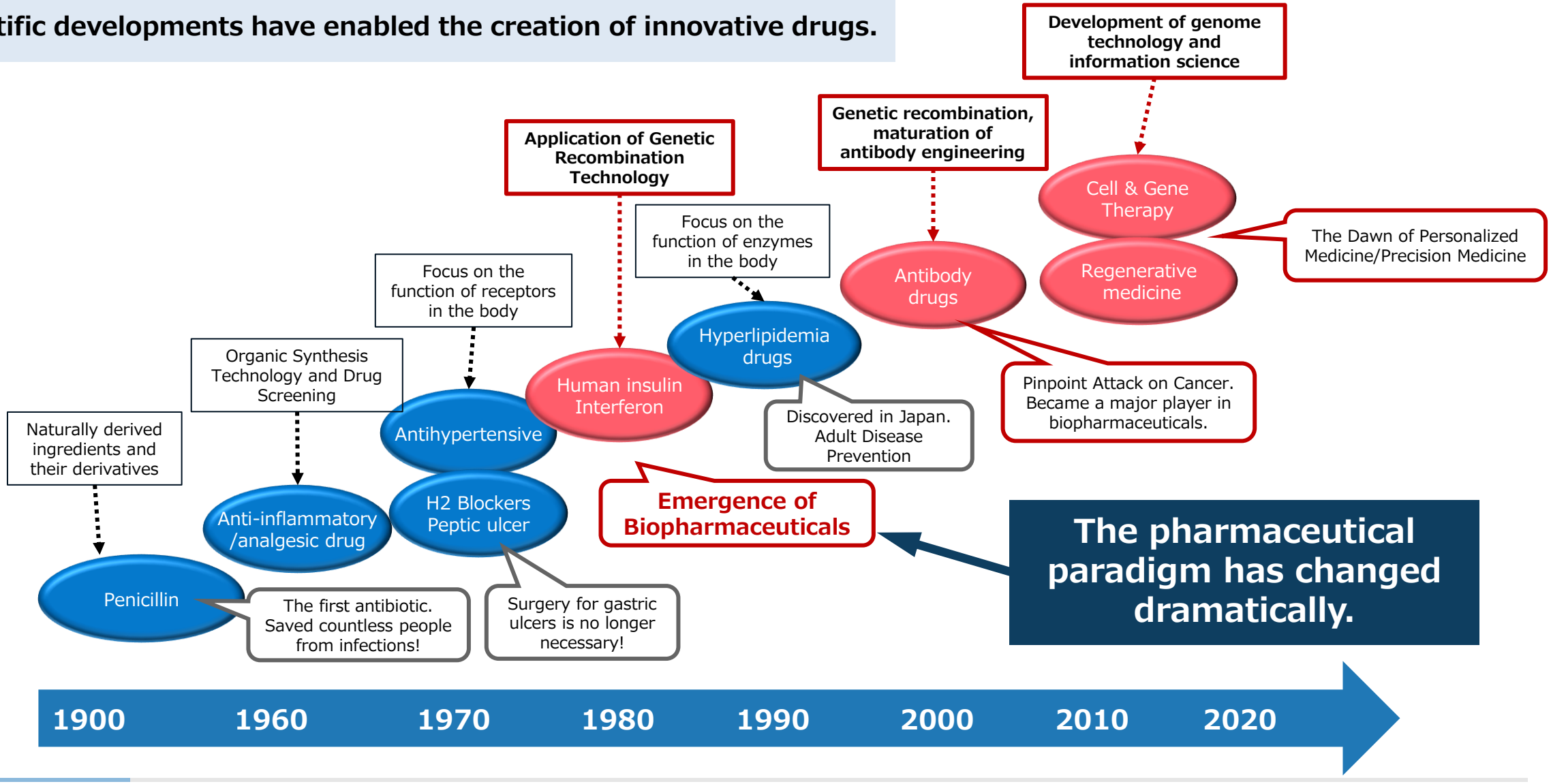
	Small molecule drugs	Biopharmaceuticals
		 Hormone protein  Antibody
Molecular size & Image	**Small** (Most are less than 500) 	**Large, Complex** (ten~hundred thousand)  
Manufacturing method (Technology)	**Chemically synthesized** (organic synthetic chemistry)	**Produced using living cells and microorganisms** (genetic engineering)
Manufacturing Quality Features	**Possible to manufacture identical products** at the molecular level (Generic drugs)	**Difficult to produce completely identical products** at the molecular level (Biosimilars)
Development Cost*	20～30 billion JPY	50～100 billion JPY
Manufacturing Cost*	–	CAPEX: 3-10 times that of small molecule drugs Quality control: 1.3-1.8 times that of small molecule drugs

＊Source: The Japan Biosimilar Association

History of Pharmaceutical Innovation and Emergence of Biopharmaceuticals

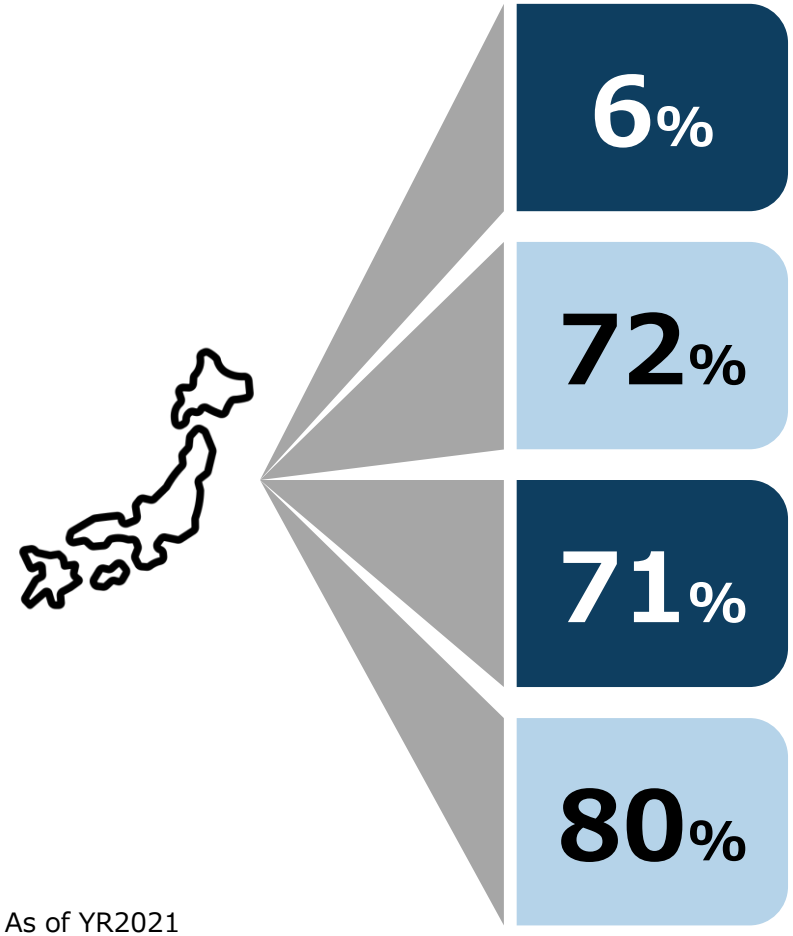
Renzoku

Scientific developments have enabled the creation of innovative drugs.



Over the past 30 years, Japan has lost its competitive edge in drug discovery.

Slow internationalization and scaling up, slow "bio-shift“, Lack of quality and quantity of start-ups



6%

Percentage of the Japanese market in the global pharmaceutical market

(the only negative growth among the 10 leading countries)

72%

Percentage of "unapproved drugs in Japan" among drugs approved in the U.S. and Europe (2016-2020)

(More than half of the "drugs not approved in Japan (56%)" in the last 10 years have no information on development in Japan.)

71%

Percentage of "biopharmaceuticals" among the world's top 50 drugs in terms of sales

(47 biotech products out of the world's Top 100, of which only 2 are from Japan)

80%

Percentage of "venture/academia-originated" drugs in global development

(In Japan, only 23% of "venture/academia-originated" drugs)

As of YR2021

A Strong Drug Discovery Ecosystem Supports Japan's Medical Security

- **Drug Discovery Ecosystem Supports Drug Discovery Capability as a Comprehensive Strength**
- **CMOs/CDMOs are key players in the drug discovery ecosystem**

■ **Deep understanding of "disease biology"**

✓ Strengthen basic life science and basic medical research

■ **Evolution and deepening of "modality"**

✓ Development of multimodality (multimodal) therapy

■ **International standard "platform technology"**

✓ Quickly create high-quality projects (seeds), and...

✓ Quickly transform the projects that are created into products.

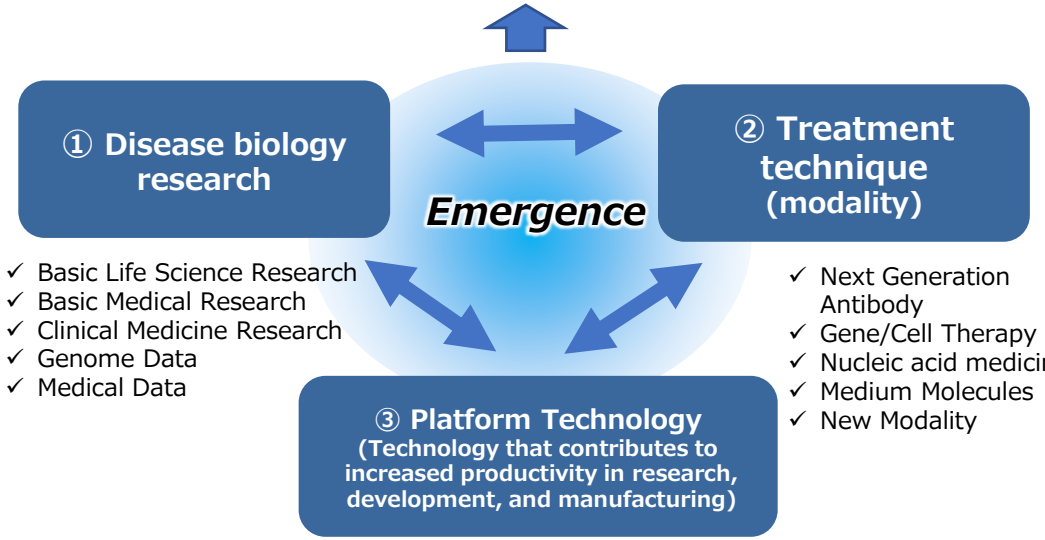
■ **"Emergent Spaces" for Fostering Innovation: Conflicts and Fusions**

✓ Formation of a global bio-community

One of the factors that contributed to the difference between Japan and others in the pandemic situation, where vaccines and therapeutics had to be delivered quickly to patients, was the difference in "production capacity" not only in the fields of "disease biology" and "modalities" but also in biopharmaceuticals in general, not just in the vaccine field.

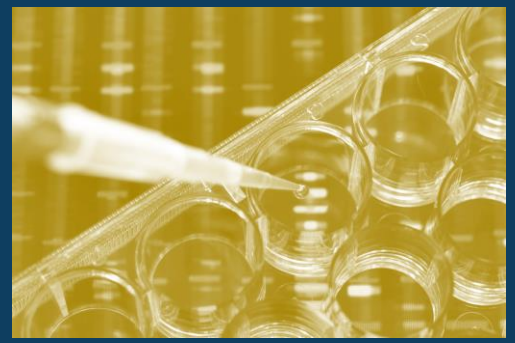
Drug Discovery Ecosystem

innovative pharmaceuticals



✓ Next-generation peripheral technologies such as IT, automation, genetic engineering, protein engineering, antibody engineering, pharmacology, pharmacokinetics, analysis, production technology, bioprocess development, and engineering that can dramatically improve "productivity" in the value chain (research, development, and manufacturing) of pharmaceutical products from seed to market

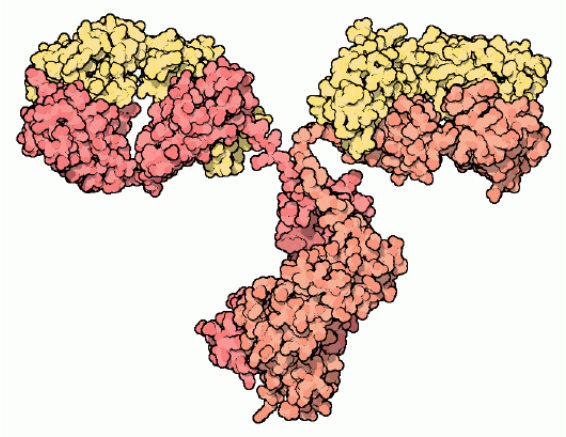
Renzoku Biologics


2. Biopharmaceutical Manufacturing and CDMOs

Monoclonal Antibodies (mAbs) are a major part of the biopharmaceuticals market

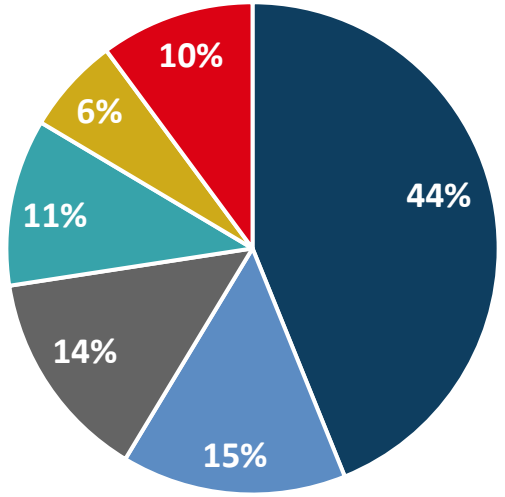
Monoclonal antibodies (mAbs) are artificially produced proteins/antibodies that can bind to specific targets in the body, often on cancer cells



History of Antibody Drug Development

1975 : Discovery of Hybridoma → Mouse Mab
1985 : Discovery of Phage display → Humanization of Ab
2010-: Advanced Ab engineering
→ Bispecific Ab, ADC, small molecule Ab

Percentage of each "modality" in biopharmaceuticals currently on the market or under regulatory review

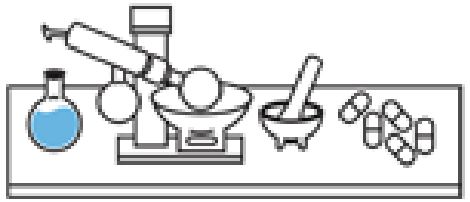


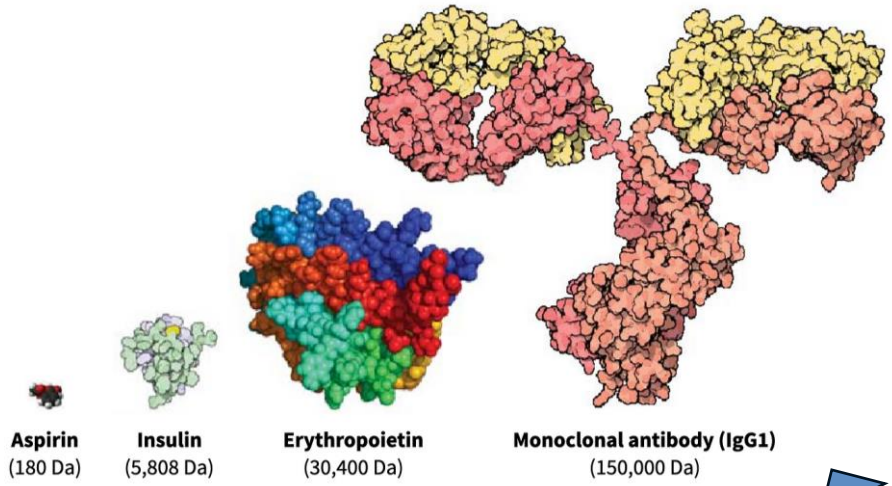
Source: BiotechGate, Ginward analysis

The emergence of biopharmaceuticals created a paradigm shift in manufacturing

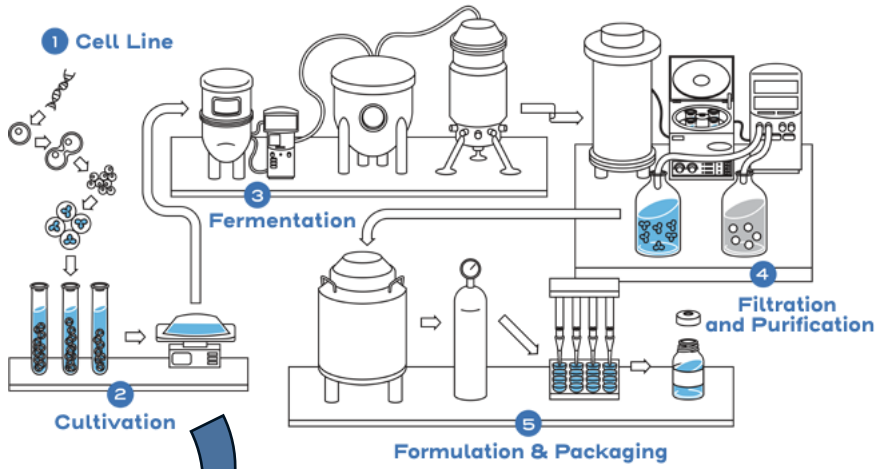
Renzoku

Small molecule drug production process





Biologics production process



From small molecules to biologics

The advent of genetic modification technology has made it possible for humans to create complex molecules that previously could only be extracted from animals, plants and other natural sources

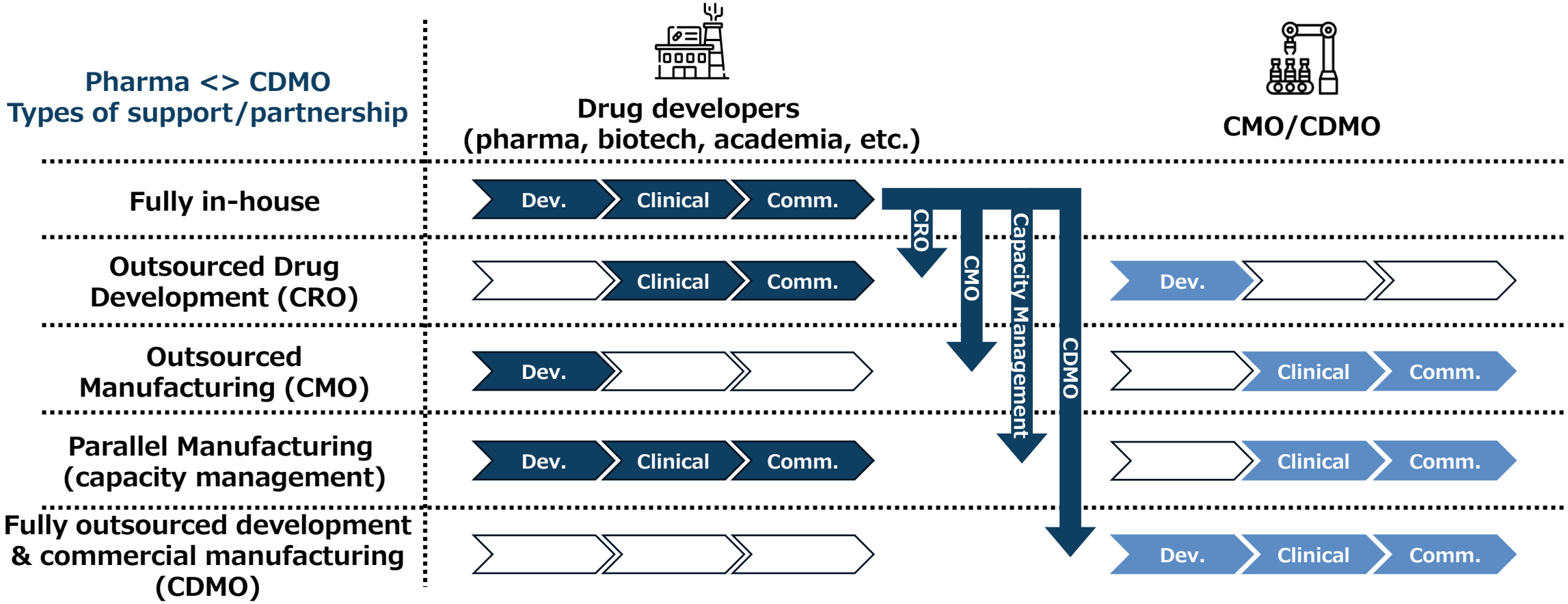
Renzoku aims to target "Continuous Manufacturing"

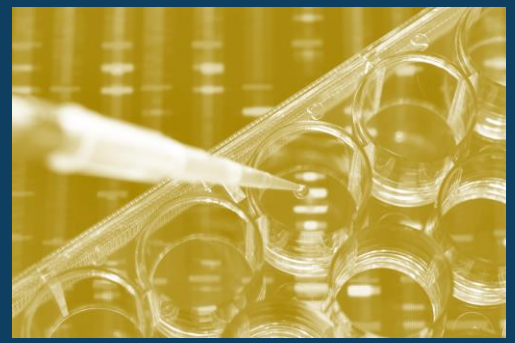
CDMOs are playing an increasing role in supporting drug developers through externalized services

Renzoku

Drivers of Horizontal Division of Labor

- Production of biopharmaceuticals requires huge initial investment, technologies and know-how that differ from those of conventional synthetic drugs
- As development costs increase dramatically, pharmaceutical companies are actively utilizing external resources (CMOs, CDMOs, CROs) to focus their resources on creating new drugs.
- Ventures play a major role in biopharmaceutical development, but those without financial resources need to outsource production




3. About Renzoku Biologics

Renzoku's Mission & Vision

MISSION

Contribute to human health and medical care around the world through innovation of biopharmaceutical manufacturing

SHORT AND MEDIUM-TERM VISION

~2026

Short-term Vision

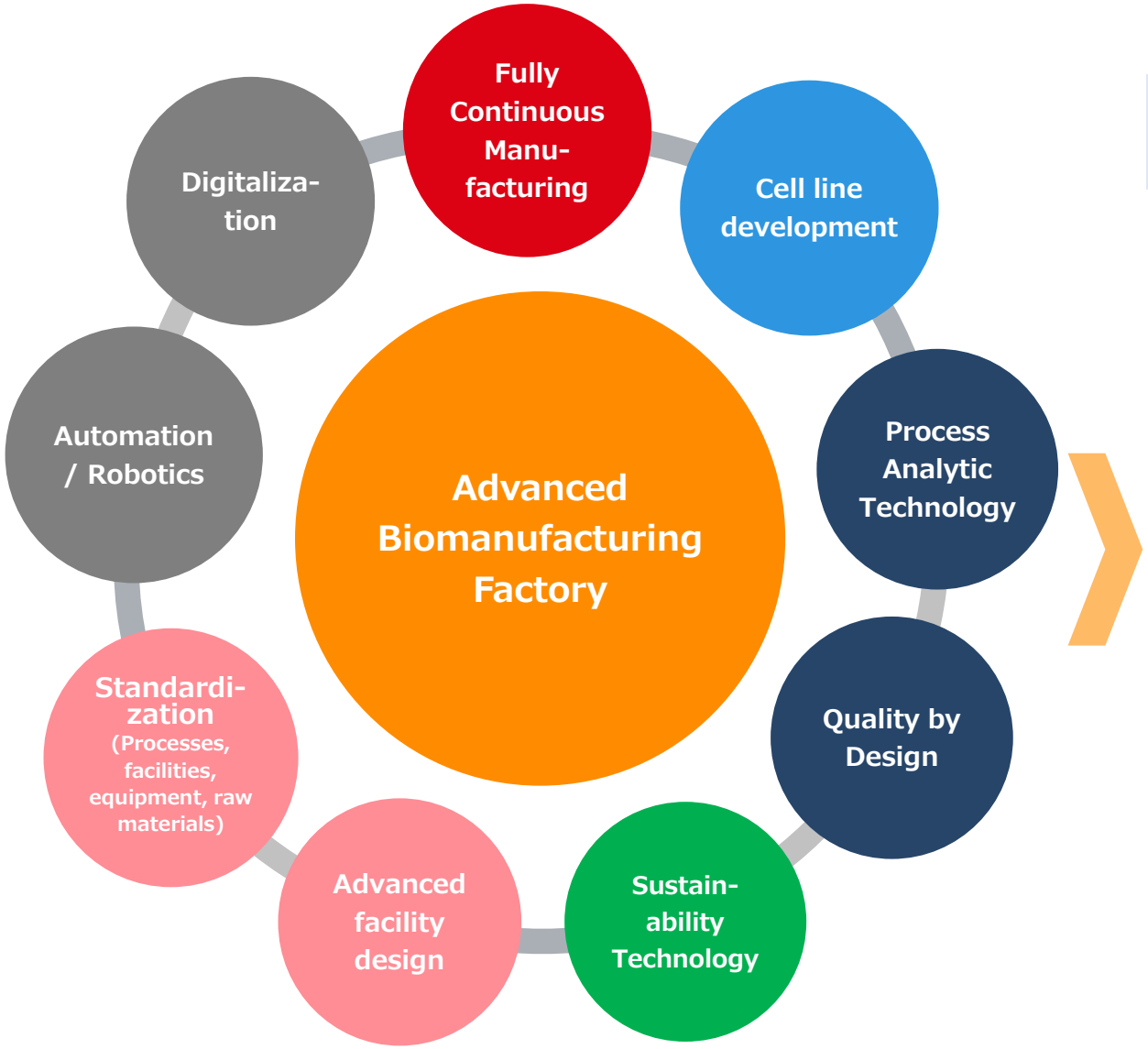
- Build GMP production capacity (50L) to enable contract manufacturing of investigational drugs.
- Leveraging advanced manufacturing technologies, including continuous manufacturing, Renzoku has laid the foundation for CDMO companies to be recognized as Centers of Excellence in biopharmaceutical manufacturing.

~2029

Medium-term Vision

- Build a facility with GMP production capacity (500L) and facilities to enable commercial production contracts.
- Expand business domestically and internationally to secure a revenue base for growth.

Realize an "advanced biopharmaceutical factory“ by integrating technologies through breakthrough innovation



“Quick & Small" realized by "Advanced Biopharmaceutical Plant”

01 Small facilities with short set-up time

Small and modular facility with shortened timeline from construction to operation

02 Target projects with small to medium volumes

Strategically targeting an underserved market in biomanufacturing

03 Flexible production plan

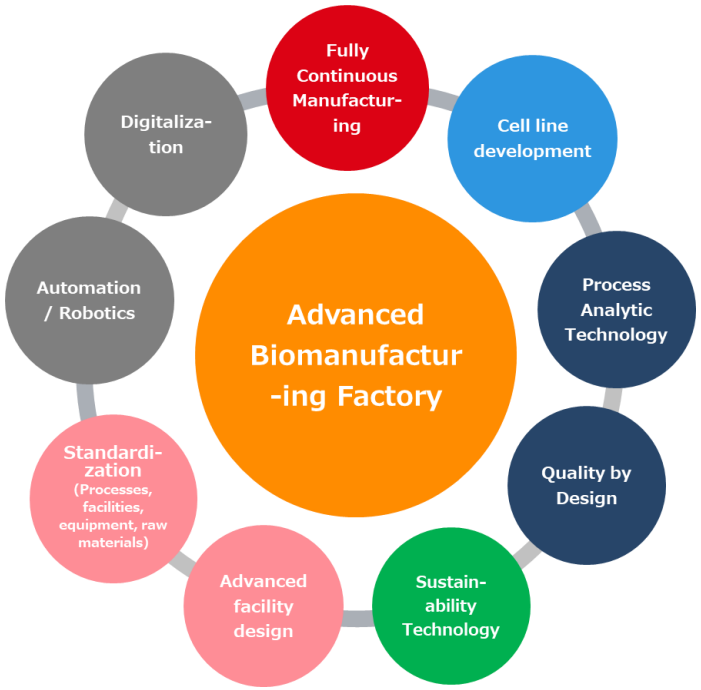
Continuous manufacturing lines can accommodate changes in production timeline

04 Low headcount requirement

Continuous biomanufacturing lines and facilities require less manpower to operate

Advanced Biopharmaceutical Plant Delivers Value to Customers

Renzoku Biologics



“Quick & Small”

- Small facilities (Small footprint)
- More easily replication of factory (cloning strategy)
- Faster technology transfer
- FIH (First In Human), Shorter lead time to market
- More flexible production scale changes
- Shorter production changeover time
- Low personnel requirements
- Manufacturing cost reduction

Drug developers
(pharma, biotech, academia, etc.)

SPEED

- Fast and flexible access to investigational drugs and finished products. Shorten time to start clinical trials and time to market.

COST

- Reduction of manufacturing costs

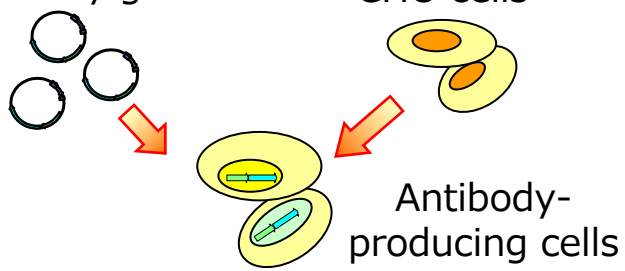
OPPORTUNITY

- Enables management of own continuous production capacity
- Easier access to investigational drugs for venture capitalists and academia, making it easier to cross the "valley of death”
- Expanded opportunities for clinical trials and commercialization of rare diseases

Antibody Drug Manufacturing Technology - Outline of Manufacturing Process -

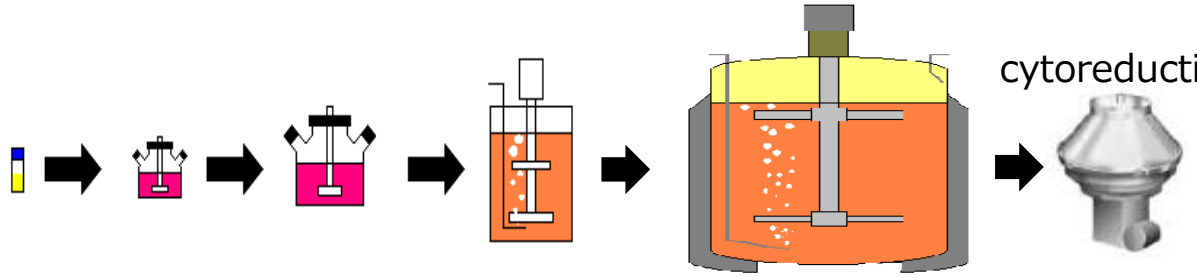
Renzoku

1. Generation of antibody-producing cell lines

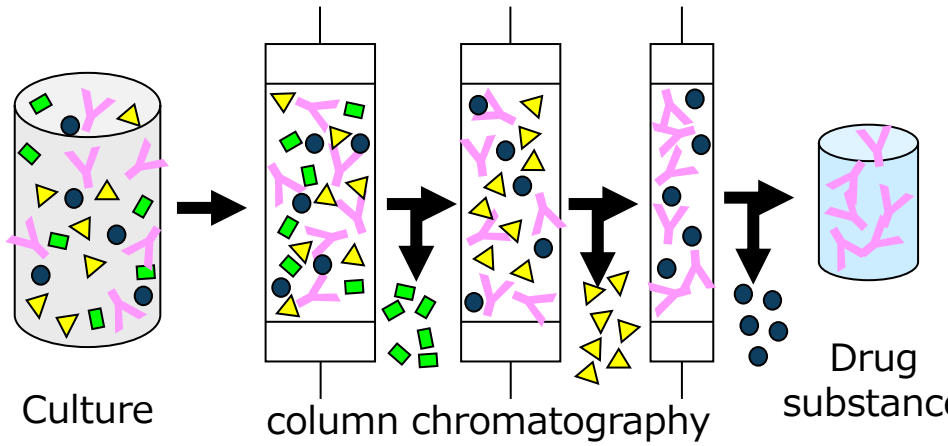


CHO cells (Chinese Hamster Ovary cells)

2. Cultivation (Upstream Process)



3. Purification (Downstream Process)

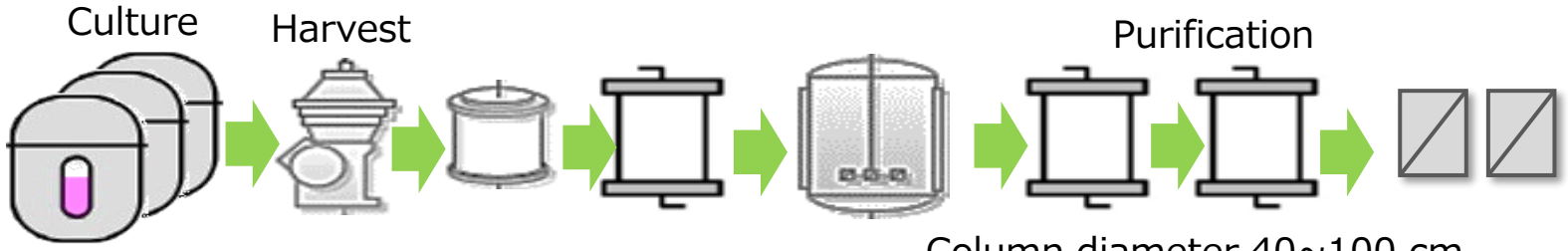


Source:
Pharm Tech Japan 2019, Vol.35 (No.4), 758-769(2019),
written by Mr. Akihiro Yanagita, Mr.Ryota Nakajima and Mr. Takuo Kawase

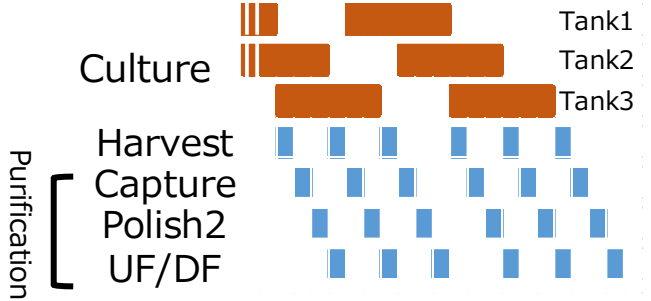
Antibody Drug Manufacturing Technology - Conventional Method (Batch) and Continuous Production

Renzoku

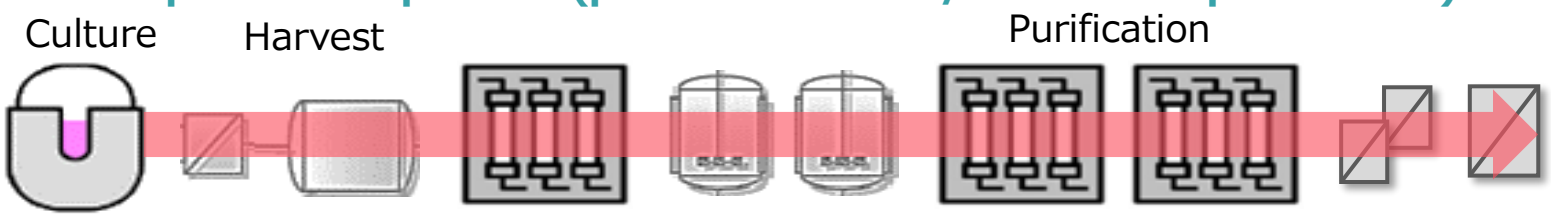
Conventional process (fed-batch culture/batch purification)



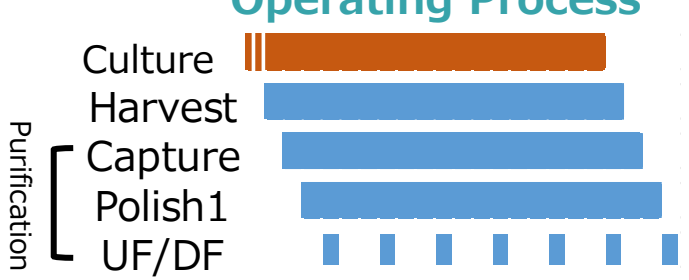
Operating Process



Continuous production process (perfusion culture/continuous purification)



Operating Process



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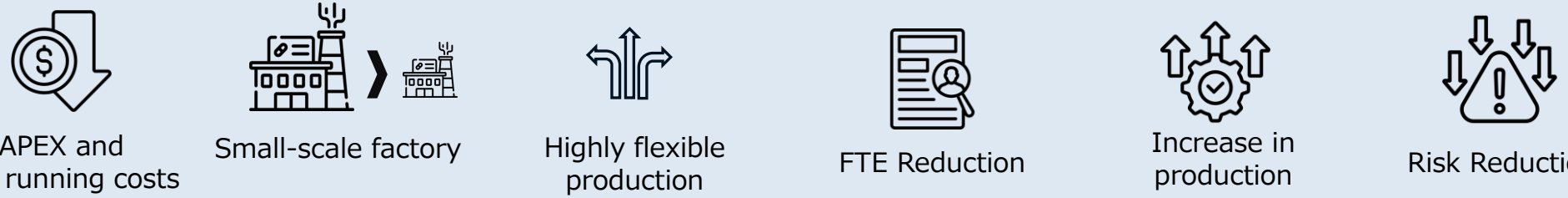


Experienced international and interdisciplinary leadership team

Renzoku

Executives

Hitoshi Kuboniwa, PhD — *CEO / Representative Director, Board Member*

Former Senior Executive Officer, Pharmaceuticals representative, Managing Executive Officer, General Manager of Pharmaceuticals Division of Chugai Pharmaceutical Co., Ltd.
More than 40 years of experience in R&D, business development, biopharmaceutical manufacturing and supply chain management in major pharmaceutical company

Fumiaki Yumoto, PhD — *Chief Operating Officer*

Former Project Associate Professor, Center for Structural Biology, Institute for Materials Structure Science, KEK, High Energy Accelerator Research Organization
More than 20 years of research experience in the U.S. (California) and Japan
Experience in supporting international business development of bio-venture companies

Teruji Yoshioka — *Chief Business Development Officer, Board Member*

24 years of global sales, factory management and overseas management experience in Germany, Taiwan and China

Junichi Kataoka — *Chief Finance Officer, Board Member*

More than 20 years of experience in finance, human resources, information systems and project promotion in Singapore, ASEAN, Europe and Japan

Advisors

Edward WILLEMS, MEng, MSc — *Chief Strategy/ Business Advisor*

Former Global Deputy Head of Capital Markets, Global Investment Bank (Crédit Agricole)
More than 30 years of cross-border and international business experience in the financial sector
13 years of experience in Life Sciences venture investments, business development, strategies, commercialization advisory

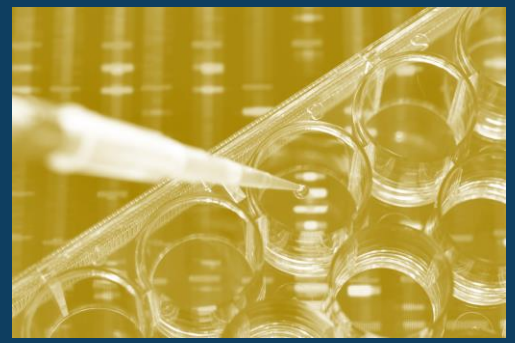
Thomas TEMPLEMAN, PhD — *Chief Technology Advisor*

Former CTO, Centessa Pharmaceuticals; SVP, Nuvation Bio; SVP, Medivation (now Pfizer); VP, Hospira (now Pfizer)
More than 40 years of experience in pharmaceutical manufacturing and supply chain, including biopharmaceuticals
13+ years in various leadership roles and obtained Six Sigma Black Belt Certification at Johnson & Johnson

Kohei Tsumoto, PhD — *Chief Science Advisor*

Professor and Vice Dean, Graduate School of Engineering, The University of Tokyo
Professor, Institute of Medical Science, The University of Tokyo
International leader in physicochemical analysis of proteins, especially in the field of antibody engineering, for more than 30 years, including former president of the Protein Science Society of Japan

Renzoku Biologics

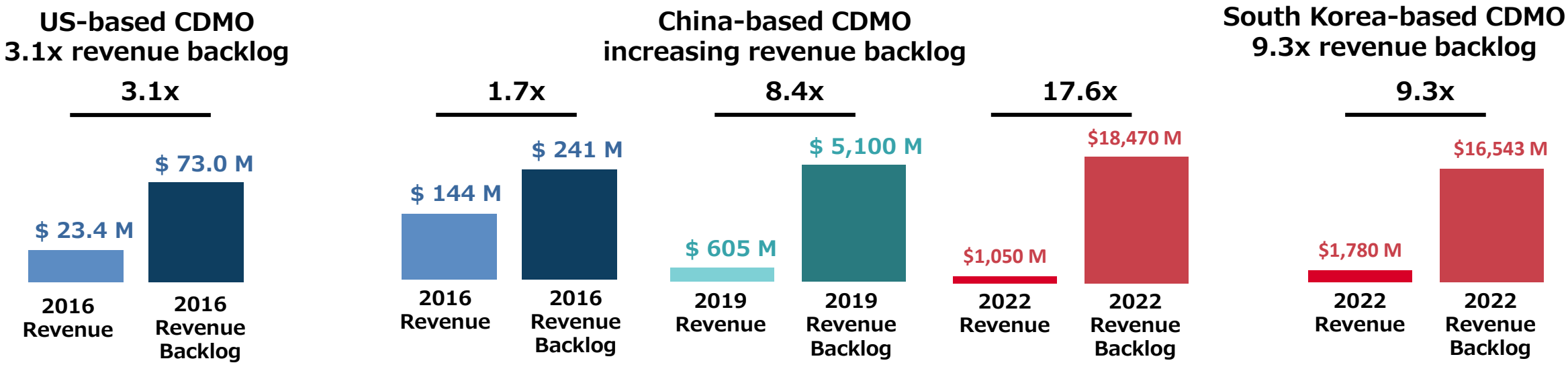




4. CDMO Market Entry Strategy

Contract biologics manufacturing is experiencing a worldwide shortage

Renzoku

Backlog in biologics CDMO was significant before COVID-19, and becoming much more severe

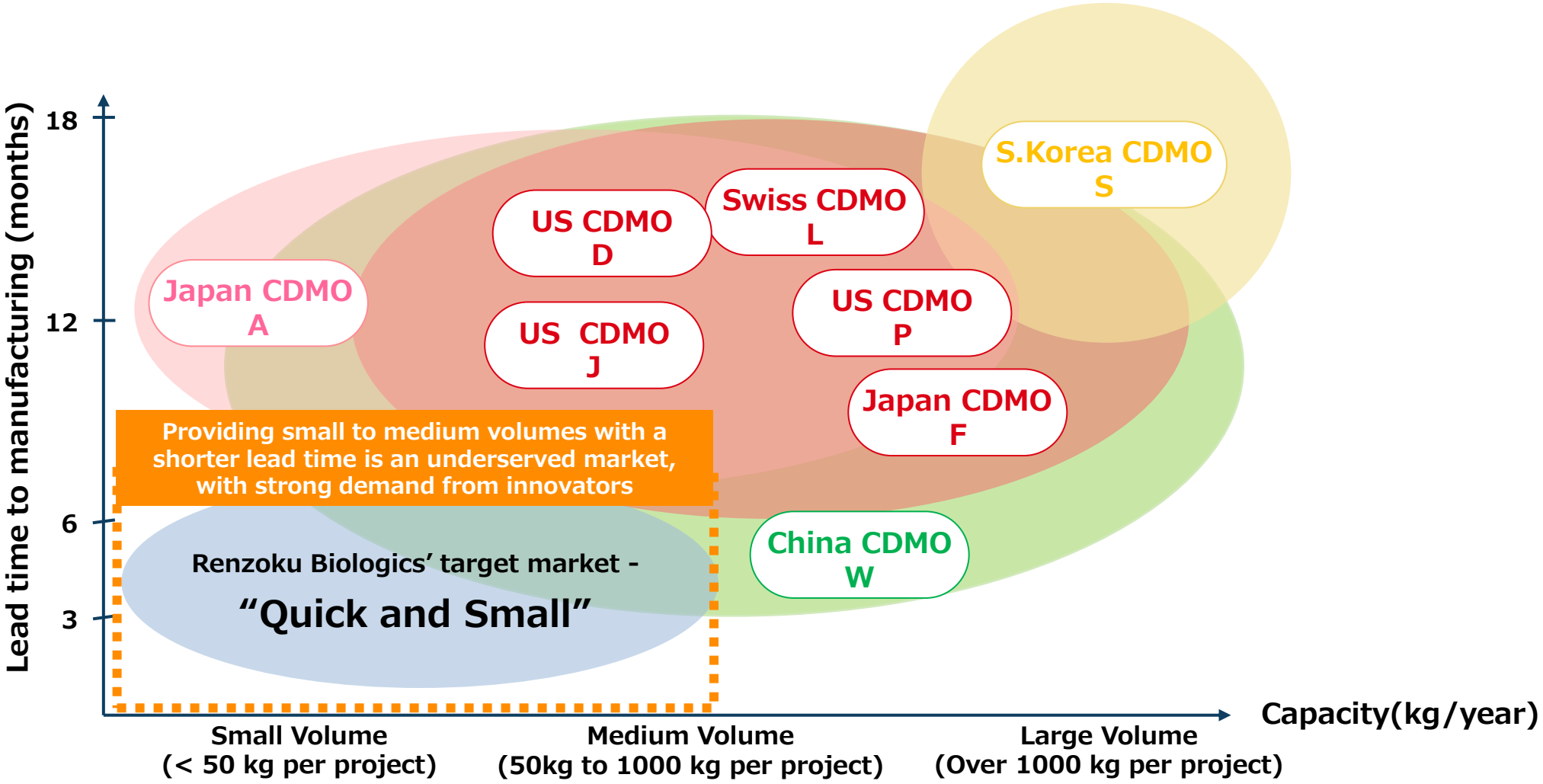


- **Companies must pay upfront to secure a schedule**, which can be a significant sum for small biotechs and academic research institutes
- Due to hundreds of ongoing clinical trials and drug launches, **CDMO capacity is stretched thin** despite aggressive expansion in recent years
  - ✓ **Waiting list of 12 to 24 months** to start process development and manufacturing after signing contracts with major manufacturers

Source: Company annual reports (2017, 2019 and 2022). Deloitte 2019 Global Life Science Outlook.

Renzoku's Strategy : Market Perspectives

Renzoku targets fast contract manufacturing for small to mid-sized volumes



Renzoku's Strategy : Technology Perspective

Depends on the customer whether to apply continuous production technology or not

Paradigm shift in biologics manufacturing

Fed batch → Intensified Fed batch and/or some perfusion → Continuous hybrid → Fully continuous process

CDMO

CDMOs focusing on conventional technologies ⟷ CDMOs active in advanced technology

- Large majority of CDMOs
- Swiss CDMO L
- Japan CDMO A
- China CDMO W
- Japan CDMO F
- US CDMO J
- Renzoku Biologics

Pharmaceutical companies

- Majority of Pharmaceutical companies
- Limited pharmaceutical companies

Pharmaceutical companies are currently cautious about applying continuous production

The important things for the use of continuous production technology are:

- Platform technologization
- Track record of sales approvals

The technology is expected to evolve toward full continuous production in the next 3-5 years.
Companies will embrace the technology in line with their business strategies

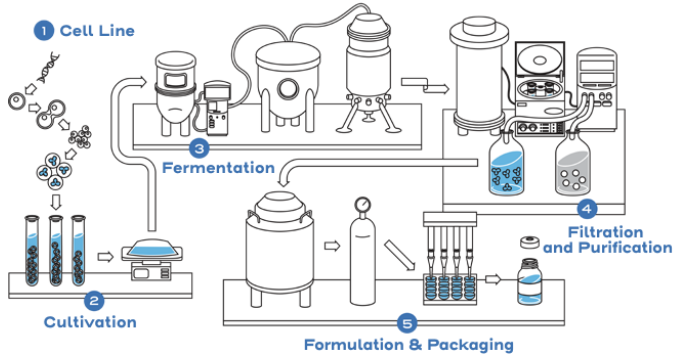
Renzoku's Expansion and Growth Strategy: Domestic and International Expansion through a "Clone Strategy"

Renzoku

Deployment of small, cloneable plants through the integration of advanced production technologies

- **Continuous Production**
- **Automation / Robotics**
- **Digitalization, advanced equipment design, standardization**

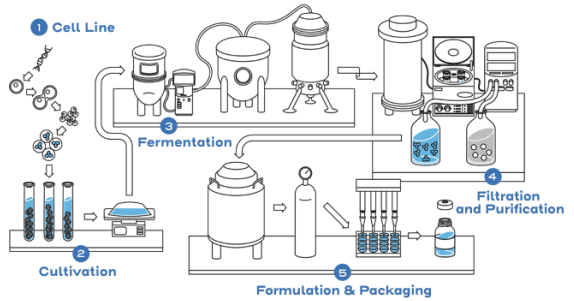
Domestic Factory



GMP Clinical use - 50L ✚ GMP Commercial use - 500L

Cloning

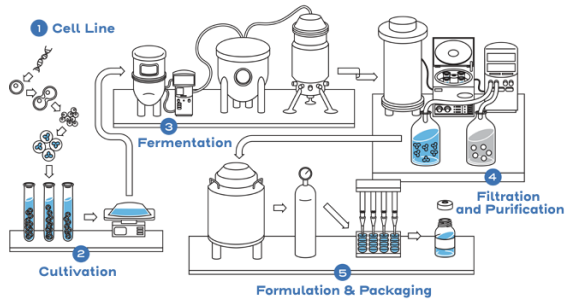
Domestic Factory



GMP Clinical use - 50L ✚ GMP Commercial use - 500L

Cloning

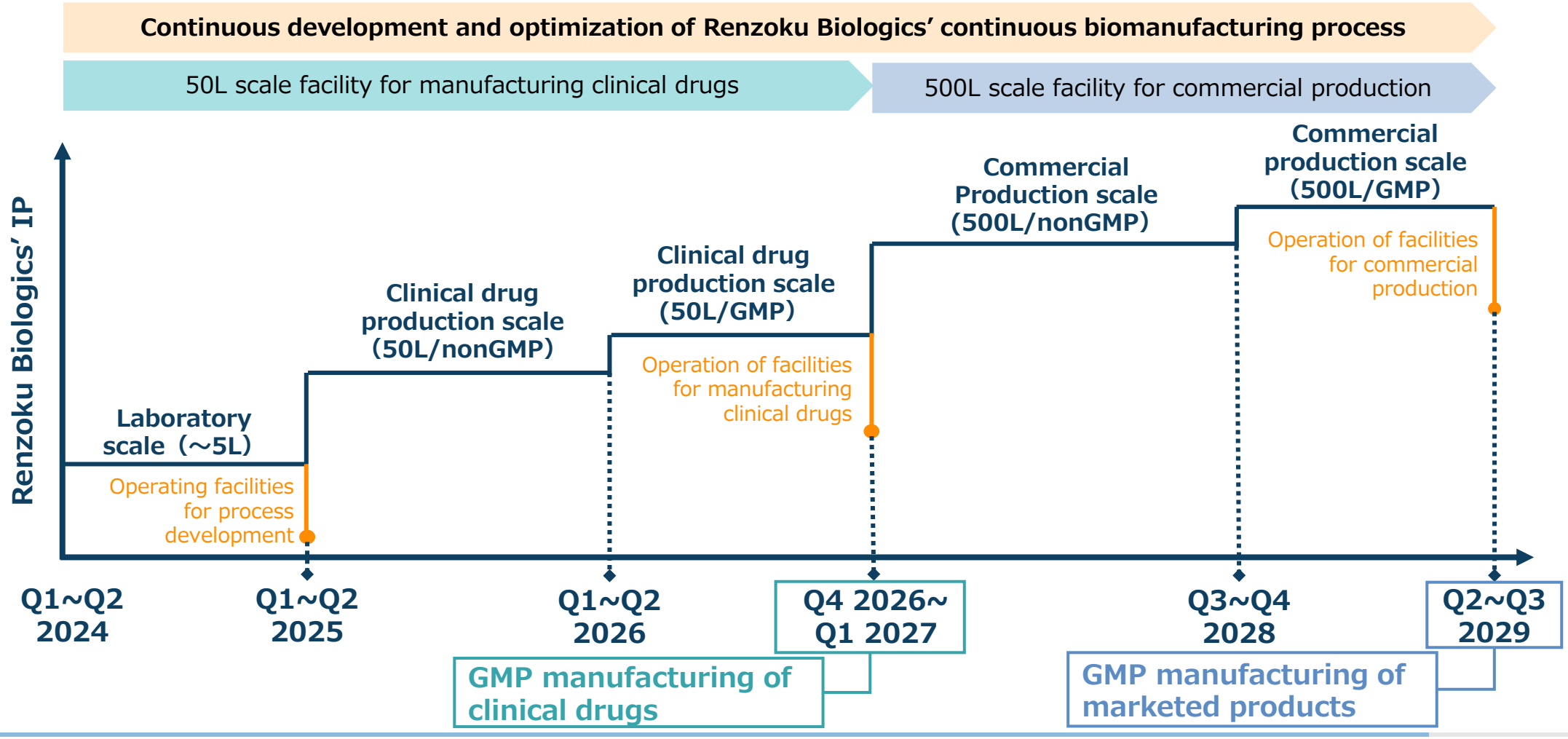
Overseas Factory



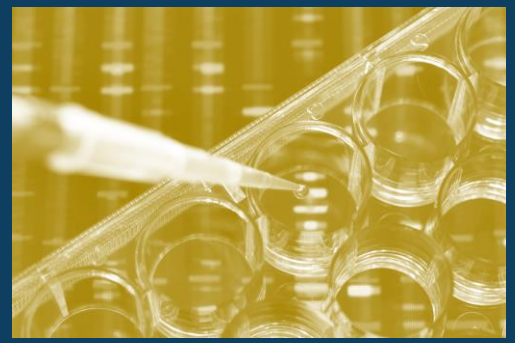
GMP Clinical use - 50L ✚ GMP Commercial use - 500L

Continuous production facility for clinical drug manufacturing in 2026 and commercial production in 2029

Accumulate own intellectual property through process development and technology acquisition through open innovation



Renzoku Biologics



5. Collaboration with SIIX Corp.

EMS and CDMOs have many things in common, and collaboration will bring synergies

Renzoku

SIIX We care.

EMS

Focus on scalability and flexibility of manufacturing facilities
High-specification manufacturing facility with airflow control
Advanced Process Development and Engineering
High demands on quality control and quality assurance
Global Supply Chain Management
Serving international and domestic clients
Manufacturing technology and software specialized for biopharmaceuticals
Correspondence with PMDA, FDA, EMA and other regulatory authorities

Renzoku Biologics

CDMO

Thank you for your attention

Renzoku Biologics Inc.

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