Chapter 05

Special Feature: Milestones and Prospects of the Bio CDMO Business

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Vision of the Bio CDMO Business

The Bio CDMO (Contract Development and Manufacturing Organization) business in the Fujifilm Group is growing as a core business, leading the world in innovative production technology and quality control.

In this Special Feature, we focus on our development milestones and future prospects and introduce our influence in the industry and future strategies.

About Bio CDMO

In the field of "biopharmaceutical," which is made by utilizing the functions of living organisms, we are entrusted by pharmaceutical companies and others to develop production processes and manufacture products. The Bio CDMO market is expected to grow at an annual rate of 15%, which is higher than the biopharmaceutical market's annual growth rate of 8% through 2030, and demand for CDMOs continues to grow.

Biopharmaceutical manufacturing sites

Biopharmaceutical

A pharmaceutical that consists mainly of proteins produced by cells and microorganisms, such as antibody drugs, gene therapies and cell therapeutics, and vaccines. While it is difficult to manufacture, it has few side effects and is expected to be highly effective for diseases that have been difficult to treat with small-molecular pharmaceuticals.

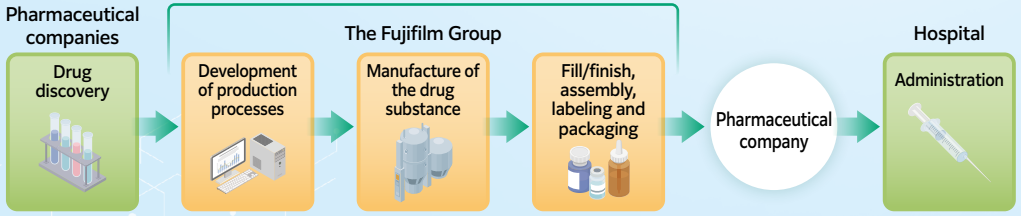
Cause cells to make drug components

Small-molecular pharmaceuticals

A pharmaceutical made by chemical synthesis. The manufacturing cost is relatively low.

Manufactured by chemical synthesis

Major roles played by the Fujifilm Group in delivering biopharmaceuticals to patients



As pharmaceutical companies increasingly concentrate their investment on new drug development, the trend toward outsourcing post-discovery processes to CDMOs is accelerating. Because the production of biopharmaceuticals is affected by subtle environmental changes, such as changes in cells, it requires advanced technology and equipment. The Fujifilm Group has the technology to develop production processes, the know-how to start up the necessary production equipment and advanced analysis technology, which contribute to the delivery of safe and secure pharmaceuticals to patients.

Message from the General Manager of the Bio CDMO business

Contributing to the stable and prompt supply of pharmaceuticals as a "reliable and true partner" for customers

Toshihisa Iida

Director, Corporate Vice President,
General Manager of Life Science Strategy Headquarters and Bio CDMO Division,
FUJIFILM Corporation
Chairman, FUJIFILM Diosynth Biotechnologies

In the pharmaceutical industry, investment in new drug candidates (pipeline) is more active than ever, and the speed required for production is increasing in order to realize the launch from clinical trials as soon as possible. In particular, demands in antibody drug markets are expanding, and pharmaceutical companies are placing importance on outsourcing to CDMOs that have sufficient track records, such as certification in each country and stable production. To win the trust of customers, it is essential to have a flexible production system that is abundant and agile.

Having development and manufacturing bases mainly in Europe and the United States, our main markets, we have the advantage of being able to provide end-to-end services that support a wide range of pipelines of pharmaceutical companies from the initial development stage to commercial production with small to medium- and large-scale manufacturing facilities. Since our entry into the Bio CDMO business in 2011, we have invested more than ¥1 trillion, including our currently announced facility expansion plan. We will continue to expand our production capacity to meet the needs of customers to scale up in line with the robust growth of the market. At the same time, we will introduce the "KojoX" approach, in which we share the designs and equipment of the Denmark site, which is highly productive and has a track record of obtaining various certifications and deploying them to other sites. This approach will enable us to quickly transfer technology between sites, ensure high-quality products and quickly obtain certifications. By fiscal 2030, we plan to increase production capacity for antibody drugs, centered on large-scale facilities, to more than 750,000 liters, more than five times the current level.

By supporting customers' efficient pharmaceutical processes, the Bio CDMO business has a social significance in being able to quickly deliver appropriate treatment to a large number of patients. As a reliable and true partner, we will pursue our vision, "Partners for Life," which aims to deliver cutting-edge pharmaceuticals with reliable quality to as many patients as possible as quickly as possible.

Biopharmaceutical Market

The Bio CDMO market will exceed the biopharmaceutical market
Growing at 15%
CAGR (2022–2030)

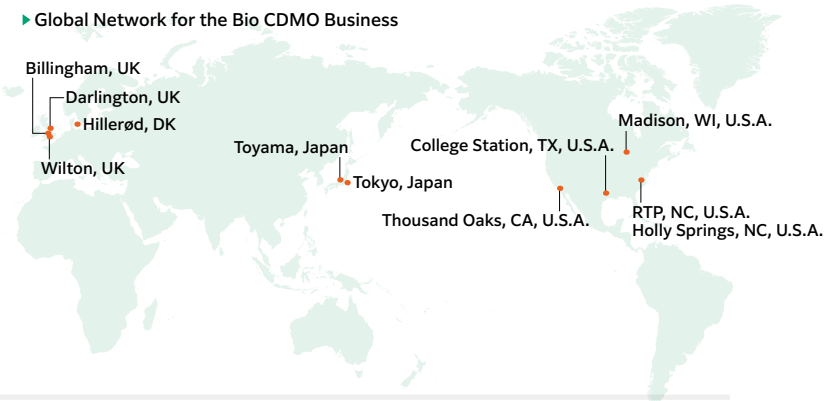
The Bio CDMO business will grow at an average annual rate of **20%** through 2030

Fiscal 2030 Target
¥700 billion

History of the Bio CDMO Business and R&D Structure

The Fujifilm Group changed its business structure in the first half of the 2000s, when the photographic film market was rapidly shrinking. We have made Healthcare and Advanced Materials the pillars of our growth and have implemented aggressive capital expenditures and M&A in both areas. As part of these efforts, since our full-scale entry into the Bio CDMO market in 2011, we have expanded our operations through the introduction and evolution of technologies cultivated in the manufacture of photographic film, such as consistent condition manufacturing technology, advanced process engineering technology, and image analysis and analytical technology. In addition, by locating our plants close to our customers' pharmaceutical companies, we are building a fast and efficient production system and responding flexibly to customer needs.

▸ Global Network for the Bio CDMO Business



History of the Bio CDMO Business

[2010s] Verification period for growth areas

We actively conduct M&A while examining and assessing areas in which we can demonstrate our superiority. We made a full-scale entry into the Bio CDMO market in anticipation of market expansion.

[2020s] Creating new value Growth period

Accelerate the creation of Group synergies and focus on creating value that has a positive impact on society. We aim to achieve revenue of ¥700 billion in the Bio CDMO business in fiscal 2030.

2010 | **2011** | 2012 | 2013 | **2014** | 2015 | 2016 | 2017 | 2018 | **2019** | 2020 | 2021 | **2022** | **2023** | **2024** | 2025 | 2026 | **2027**

2011
Acquired MSD Biologics/Diosynth and entered the Bio CDMO market

Currently FUJIFILM Diosynth Biotechnologies UK

Currently FUJIFILM Diosynth Biotechnologies U.S.A.

2014
Acquired Kalon Biotherapeutics and entered the Vaccine CDMO market

Currently FUJIFILM Diosynth Biotechnologies Texas

2019
Acquired Biogen (Denmark) Manufacturing and accelerated growth of the Bio CDMO business

Currently FUJIFILM Diosynth Biotechnologies Denmark

2022
Acquired the manufacturing site of Atara Biotherapeutics and entered the cell therapies CDMO market

FUJIFILM Diosynth Biotechnologies California

2023
Large facility built in Wisconsin

FUJIFILM Cellular Dynamics

2024-
Expanding large-scale tank facilities in Denmark and North Carolina

FUJIFILM Diosynth Biotechnologies Denmark

FUJIFILM Diosynth Biotechnologies North Carolina

2027
Establish Japan's first Bio CDMO site

FUJIFILM Toyama Chemical

R&D Structure of the Life Sciences Field

With the Bio Science & Engineering Laboratories as our core research laboratory, we are advancing medium- to long-term R&D based on the core technologies cultivated in our photographic film business, incorporating the needs of customers and markets from Group companies in Europe and the United States, which are close to our customers' bases. In addition, we are strengthening our global R&D structure while promoting personnel exchanges, such as collaborating with researchers overseas on R&D for implementation at Group companies.

Bio CDMO business

FUJIFILM Diosynth Biotechnologies

FUJIFILM Toyama Chemical

Human resources Know-how

Research and development

FUJIFILM Wako Pure Chemical

FUJIFILM Bio Science & Engineering Laboratories

FUJIFILM Toyama Chemical

Human resources Know-how

Life Sciences business

FUJIFILM Cellular Dynamics Bio Science and Engineering Laboratories in the U.S.

FUJIFILM Irvine Scientific

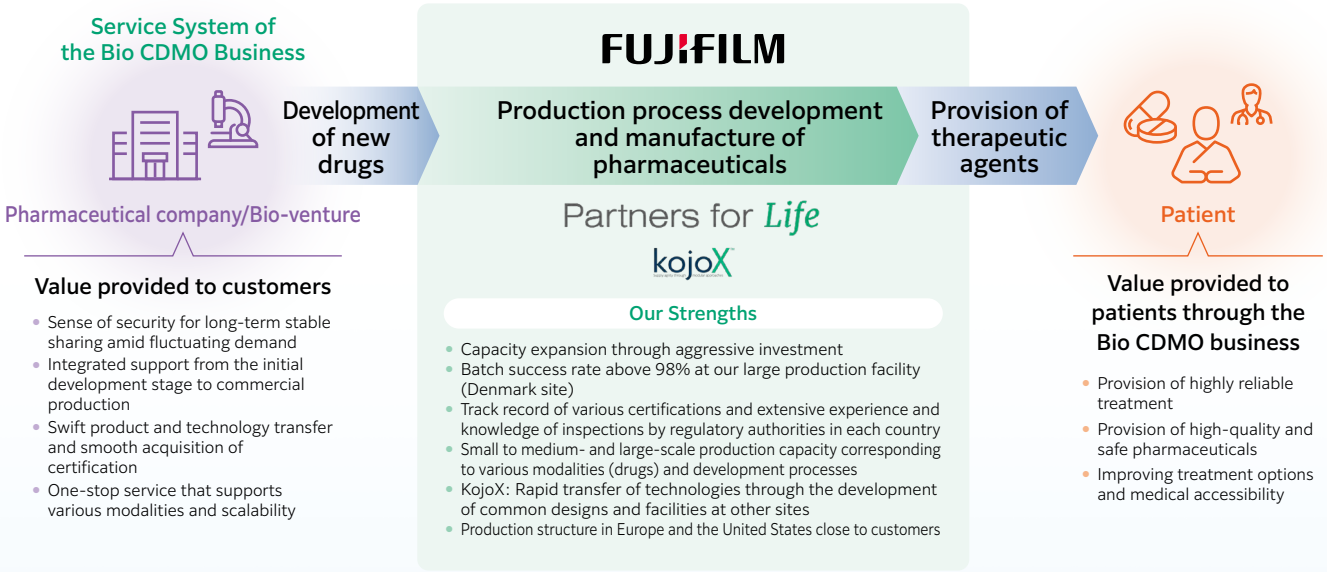
Business Strengths (1)

Partners for Life and KojoX

Basic Policy

As the population ages, there are still many medical needs for diseases for which there is no effective treatment. The Fujifilm Group is accelerating its efforts to realize its "Partners for Life" vision, which aims to deliver state-of-the-art pharmaceuticals with high quality, faster and to as many people as possible in Bio CDMO and other Life Sciences areas, as a "trusted and true partner" that works closely with pharmaceutical companies and patients.

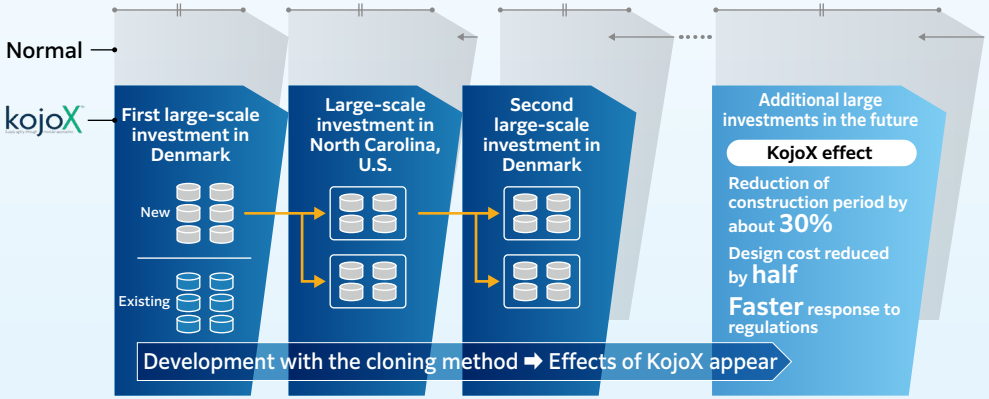
In addition to focusing on end-to-end services that provide integrated support from the initial stages of development to commercial production of a wide range of drugs of pharmaceutical companies, we will expand the range of solutions that can be provided to customers by sharing production technology that can respond to various pharmaceuticals and our abundant experience and knowledge on inspections by regulatory authorities in various countries among Group companies and creating synergies.



Realized Rapid Transfer of Technology by KojoX, Where Common State-of-the-Art Equipment Is Deployed to Other Sites

Fujifilm aims to achieve high-quality products and shorten construction lead times by quickly transferring technologies between sites and by augmenting facilities through the KojoX approach. This approach involves sharing designs and facilities with the Denmark site of FUJIFILM Diosynth Biotechnologies, which is highly productive and has a track record of obtaining various certifications and deploying them to other sites.

At present, in addition to the six 20,000-L Mammalian cell culture tanks currently in operation at the Denmark site, construction is proceeding with the facility expansion of 14 tanks (the first phase: six tanks scheduled to start operation in fiscal 2024; the second phase: eight tanks scheduled to start operation in fiscal 2026) and the introduction of 16 tanks (the first phase: eight tanks scheduled to start operation in fiscal 2025; the second phase: eight tanks scheduled to start operation in fiscal 2028) at the North Carolina site in the United States. Under the KojoX approach, the equipment, design, production flow, and systems from the Denmark site are transferred to the North Carolina site in the form of clones. Improvements made at the North Carolina site are then transferred to the secondary investment at the Denmark site. As a result, the construction period is reduced by about 30% and the design cost is reduced by about half. At the same time, it is possible to quickly transfer technologies and acquire various certifications.



Business Strengths (2)

Industry-Leading Technology and Manufacturing Experience

The Fujifilm Group's Bio CDMO business has introduced "high-quality production technologies," which were cultivated in the manufacture of photographic films and continues to manufacture products incorporating process-engineering technologies and image analysis technologies with the goal of productivity improvement. Through these multifaceted initiatives, we are taking the lead in technological innovation in a wide range of advanced therapies areas, from antibodies to cellular and gene therapies.

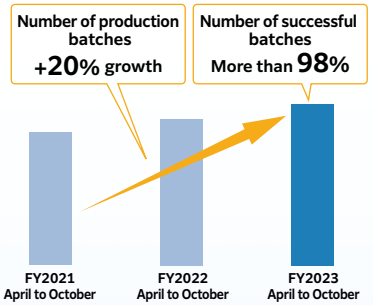
Manufacturing Results at Denmark Site

Our site in Denmark has high productivity and an extensive record of inspection response. The number of production batches of existing tanks increased by 20% from 2021 to 2023. The success rate exceeded 98%, which has been highly evaluated by customers.

In addition, all inspections conducted by the regulatory authorities of various countries, where our biopharmaceuticals are distributed, having solid compliance systems and facilities since 2011. We have earned the trust of the U.S. Food and Drug Administration (FDA) for its track record, and 25% of pre-approval inspections by the FDA are exempted from on-site inspections.

Number of production batches

Realization of highly efficient and stable manufacturing



Extensive experience in responding to inspections

- **Number of acceptance of inspections by regulatory authorities in each country:**
  35 in total (since 2011) All got positive results
- **Building trust with regulatory authorities by accumulating a track record**
  25% of PAI*1 by U.S. FDA were approved with the exemption from on-site inspection

*1 Pre-approval Inspection

Systems for Batch and Continuous Manufacturing

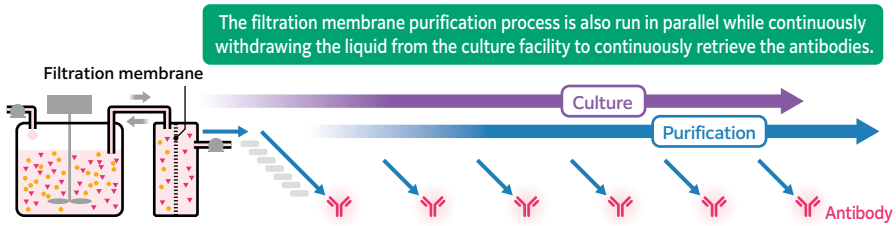
In drug substance manufacturing of biopharmaceuticals, there are complex processes including a culture process in which mammalian cells are grown in a culture media serving as a nutrient in a culture tank to produce protein until harvest, and then a purification process in which impurities such as cells and their waste products are removed in order to extract the proteins.

For the first time in the industry*2, we have constructed a 500-L continuous manufacturing system that enables continuous, integrated production of drug substances by linking all processes from cultivation to purification, which is the manufacturing process of drug substances for biopharmaceuticals. It is possible to continuously and efficiently produce high-quality drug substances by suppressing the degradation and deterioration of antibodies over time. We are currently developing the industry's first 2,000-L integrated continuous manufacturing system. We are also aiming to further improve productivity in large-scale facilities by applying this technology to the pre-incubation of 20,000-L production.

*2 According to a survey by Fujifilm

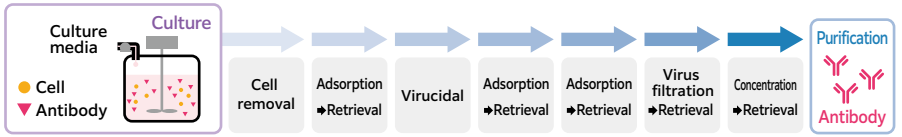
Continuous manufacturing

A manufacturing method that contributes to improvements in efficiency and productivity through the continuous supply of materials and uninterrupted operation of product manufacturing processes.



Batch manufacturing

A mainstream production method in which raw materials are put in at the beginning of the manufacturing process, and after one process is completed, the products obtained there are taken out and we proceed to the next process. It is expected that there will be less labor to change the production process and less loss than producing a variety of products in small quantities.

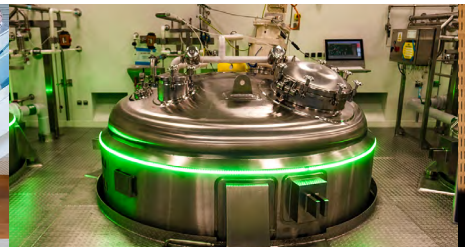


Development of Next-Generation Biopharmaceuticals

In addition, we are proceeding with the development of production technologies to strengthen our response to the next-generation antibody drug, "Antibody Drug Conjugate (ADC)," which is expected to grow in the future, as well as "cutting-edge therapeutic areas such as cellular and gene therapies."

Messages from the Members of FUJIFILM Diosynth Biotechnologies





Your Trusted Partner for Life in the Biopharmaceutical Industry

Lars Petersen
President & Chief Executive Officer

The 2030 Partners for Life strategy outlines our vision of being a true partner, where clients are willing to trust us with their entire portfolio across the full drug life cycle and end-to-end value chain—
transforming the CDMO industry.

We will become Partners for Life and transform the industry by focusing on three key pillars.

Putting people first:

We encourage everyone to bring their full selves to work to create trust and diversity. We lead and empower our people to take ownership, and we invest in creating a culture where people can flourish. We do that through our nine People Fundamentals that underpin our unified approach to how we show up, how we interact and how we lead across our organization.

Transforming the industry through our KojoX philosophy:

We are building the next level of global modularity giving our customers everything they need with just one partner. With this approach, we can develop and commercialize treatments and therapies effectively and efficiently, and together make patients' lives better.

Unprecedented delivery:

Trust is built on years of keeping our promises! We are dedicated to achieving unmatched delivery and security of supply, reinforcing the trust and confidence of our employees, partners, regulatory authorities and owners.

Enabling Operating as One Organization by Driving Site-Agnostic and Consistent High-Quality Experiences

Charlotte Kornbo
Vice President
Global Quality Operations & Systems

We demonstrate our trustworthiness to our partners by embedding a quality mindset across our entire network. Our foundation is based on easily understood principles focusing on patient safety and systems that enable seamless business operations.

- Honest and transparent collaboration
- Platform guidelines that structure and simplify KojoX implementation
- Consistent GMP operations through value-added state-of-the-art systems and adopting a continuous improvement ethos

Committed to Delivering New Capacity

Jordan Ulrich
Vice President,
Project Delivery

We have been entrusted with an incredible opportunity to deliver one of the largest greenfield cell culture bio-manufacturing facilities in North America. Though still under construction, we have already secured significant client commitments, making it critically important to make this facility operational on time. It is an enormous responsibility that the team and I are committed to delivering successfully.

Our commitment is shown through the energy and enthusiasm (*Genki*) with which we tackle challenges and create solutions each day. We show it by creating a culture that empowers people to both lead and hold each other accountable. We take pride in living up to our commitments, and we look forward to successfully delivering a facility that will manufacture life-impacting medicines to make patients' lives better!