Next Step

SEIKAGAKU CORPORATE REPORT 2024

SEIKAGAKU CORPORATION

Exploring the Innovative Promise of Glycoscience

Seikagaku Corporation is a pharmaceutical manufacturer with a history of more than 70 years. As a pioneer in glycoscience, a research field with enormous hidden potential in drug discovery, we create innovative pharmaceuticals and medical devices.

Seikagaku contributes to the health, well-being, and improved quality of life for patients around the world in order to create a prosperous future.

What is Glycoscience?

Glycoscience is a field of research into sugar chains and the complex carbohydrates, or glycoconjugates, that are formed through the binding of these sugar chains with other substances, such as proteins and lipids. Research in this field has demonstrated that sugar chains are deeply involved exchanges of information and substances among cells and are essential for various life phenomena, from the creation of life to aging.

There is also growing interest in the relevance of sugar chains to numerous diseases. Progress in the field of glycoscience is expected to lead to the development of new diagnostic methods and therapies.

Key roles of sugar chains

1. **Creation of life through fertilization**
   Sugar chains are involved in the fertilization process that occurs when a sperm encounters an egg.
2. **Determining blood type**
   The ABO blood type of a person is determined by the shape of sugar chains on the surface of their red blood cells.
3. **Water retention**
   Sugar chains, such as hyaluronic acid, protect cells against excessive water loss.
4. **Cell growth control**
   Sugar chains control the activity of certain growth factors.
5. **Protecting the body against external enemies**
   When a viral or other infection invasion occurs, sugar chains activate immune cells by stimulating macrophages, which are a type of white blood cell.

Sugar chains and diseases

1. **Viral and bacterial infections**
   Pathogens such as the influenza virus bind to specific sugar chains on a cell's surface before penetrating the cell itself.
2. **Metastasis of cancer**
   When cells become cancerous, their sugar chains change shape and start to accelerate the proliferation and metastasis of cancer cells.
3. **Diabetes**
   Abnormal sugar chain genes are believed to be one of the causes of this disease.

<Reference> It has been found that highly metastatic cancer cells feature an increased amount of giant sugar chains, which are much less prevalent in normal cells.



Our Strengths

Source of Competitiveness

Seikagaku Corporation has developed a unique business model based on specialization in R&D and manufacturing. We contribute to medical care globally by developing and supplying high-quality pharmaceuticals and medical devices that leverage our unique technological capabilities.

1 Specialization in Glycoscience

Since its foundation, Seikagaku has focused its attention on the importance of glycoscience and has been working on applied research for new drug development. With our many research achievements, we are contributing to advances in medical science globally through our pioneering and specialized work in this niche field.

2 State-of-the-Art Technology Related to GAG*

Through its many years of glycoscience research, Seikagaku has built up a library of GAG compounds and GAG-related enzymes, as well as a wide range of technologies based on the manipulation of these substances. We use these resources to develop new drugs. In its manufacturing operations, we apply our original GAG-related technologies and expertise to various processes, such as extraction, purification, and culturing.

*GAG: Glycosaminoglycans, such as hyaluronic acid and chondroitin sulfate, which are structural components known as glycoconjugates.

3 Unique Business Model Specialization in R&D and Manufacturing

Seikagaku does not have its own sales force. Instead, we offer our products through sales partners that have strengths in their respective product fields. This approach allows us to concentrate our management resources into R&D and manufacturing. This is evidenced by the fact that our R&D expenses account for 20% to 30% of net sales, and that 35%* of our employees are involved in R&D.

*Non-consolidated basis.

Philosophy

CORE VALUES

<MOTTO>

Creativity, Fairness, Dreams and Passion

<Creed>

We create safe and useful products for human well-being with basic research based on glycoscience.

<Guidelines for Our Activities>

- We create a corporate environment of mutual trust and communication using individual abilities.
- We create innovative and useful products through in-depth cooperation between industrial and academic circles.
- We assure the highest quality and safety of our products.
- We enhance interaction with society by establishing genuine trust.

Through these efforts, Seikagaku will strive to become a sound and socially responsible company that protects the natural environment and improves quality of life.

Inspiration Behind Our Motto

Creativity

Individual and corporate creativity are important for scientific advancement aimed at pursuit of truth. We can produce novel new products, new technologies, and new use of products by developing and applying unique and creative approaches, thus we can expect to achieve sound and stable corporate growth as a result of these efforts.

Fairness

We will adhere to principles of fairness that are recognized worldwide, and through self-discipline, will ensure we remain a company that is respected by society at large. Our “Creativity” and our “Dreams and Passion” must be built on a foundation of “Fairness.”

Dreams and Passion

We have high ambition, and strive to achieve our dreams by working toward our ideals. This is the ultimate source of growth for our employees and our company.

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≪ Editorial Policy ≫

The Seikagaku Corporate Report 2024 is an integrated report containing both financial data and information about environmental, social, and governance (ESG) initiatives. Non-financial information includes the history of our growth, our value creation processes, and initiatives in various business areas.

This report was created with the aim of providing stakeholders with a fuller understanding of our business activities and the value provided by Seikagaku Corporation.

<Target audience>
Seikagaku stakeholders, including shareholders and investors.

<Period covered by the report>
This report covers fiscal 2023 (April 1, 2023–March 31, 2024), but it also includes references to activities in fiscal 2024.

Our History

Success Based on Steady Pursuit of a Unique Vision

As indicated by the company name, Seikagaku Corporation focuses on research in the field of biochemistry (seikagaku in Japanese). The history of Seikagaku Corporation is a story of growth in step with the development and progress of glycoscience.

Major Product Timeline

1950

Start of manufacture and sales of chondroitin sulfate for pharmaceutical products, following approval for pharmaceutical manufacturing in Japan



1960

Start of manufacture and sales of glucide-related research reagents developed in-house

*The research reagent business was terminated in 2012

1981

Start of manufacture and sales of world's first endotoxin colorimetry reagents

1987

Launch of ARTZ®*, the world's first joint function improving agent with hyaluronic acid as its main active ingredient
Launch of OPEGAN® as the first Japanese-made ophthalmic viscoelastic device



*The joint function improving agent ARTZ® delisted from the NHI drug price standard on March 31, 2022

1992

Launch of ARTZ®, a joint function improving agent, in Sweden under the name "Artzal®," making the start of full-scale overseas marketing of joint function improving agents

1993



Launch of ARTZ Dispo®, a joint function improving agent

1995



Launch of OPEGAN Hi® (now Sodium Hyaluronate 0.4 Ophthalmic Viscoelastic Preparation 1% SEIKAGAKU), an ophthalmic viscoelastic device

2001

Launch of SUPARTZ®, a joint function improving agent, in the U.S. (now SUPARTZ FX®)



2007

Launch of MucoUp®, a submucosal injection agent for endoscopic surgery



2012

Launch of Gel-One®, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, in the U.S.



2016

Launch of SHELLGAN®, an ophthalmic viscoelastic device



2018

Launch of HERNICORE®, a treatment for lumbar disc herniation



2019



Launch of HyLink®, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis in Italy

2021



Launch of JOYCLU®, a joint function improving agent

Business Structure Timeline

1940s~

The world's first company to successfully produce chondroitin sulfate on a commercial scale.

1947

Kosei Suisan K.K. (now Seikagaku Corporation) is established and opens the Kurihama Office (now Kurihama Plant) in Yokosuka City, Kanagawa Prefecture



1949

Masakane Mizutani (a former President of Seikagaku Corporation) commences trial production with the aim of realizing the world's first production of chondroitin sulfate on a commercial scale

1970s~

Pharmaceuticals using hyaluronic acid are developed.

1960

The Tokyo Research Institute (renamed the Tokyo Research Center in 1966) is opened in Shinjuku-ku, Tokyo

1962

The Company changes its name to Seikagaku Corporation

1968

The Tokyo Research Center (now the Central Research Laboratory) is relocated to Higashiyamato City, Tokyo



1975

The Takahagi Plant is opened in Takahagi City, Ibaraki Prefecture

1989

The Company's stock is registered on the Japan Securities Dealers Association market



1990s~

Enhances its range of pharmaceuticals using hyaluronic acid and expands its activities in overseas markets.

1997

Seikagaku Corporation acquires Associates of Cape Cod, Inc. (U.S.A.), a manufacturer and seller of endotoxin-detecting reagents, etc.



1998

ISO 13485 certification is achieved

2004

Seikagaku Corporation is listed on the Second Section of the Tokyo Stock Exchange

2005

Seikagaku Corporation is promoted to the First Section of the Tokyo Stock Exchange

2013

The CMC Research Laboratory is established in Higashiyamato City, Tokyo (on the same site as the Central Research Laboratory)

2018~

Product diversification leveraging cutting-edge glycoscience technology. Toward a new stage.

2020

Seikagaku acquires CDMO* business operator Dalton Chemical Laboratories, Inc. (Canada)



*CDMO: Contract Development and Manufacturing Organization
A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions

2022

SEIKAGAKU NORTH AMERICA CORPORATION is established in Canada to manage pharmaceutical and medical device development in North America

Moved to the Tokyo Stock Market, Prime Market

Business Activities and Products

Seikagaku has two business segments. In the Pharmaceuticals business, we offer a range of original products that leverage technologies and knowledge cultivated over many years as a glycoscience pioneer. In the LAL business, we offer endotoxin-detecting reagents and other products.



LAL Business

Seikagaku engages in the LAL business, manufacturing and selling endotoxin-detecting reagents used in quality control of pharmaceutical and medical device manufacturing processes as well as a beta-glucan-detecting in vitro reagent for the diagnosis of deep fungal infections.

What are endotoxins?

Endotoxins are one of the major components of the outer membrane of gram-negative bacteria and exhibit strong pyrogenic activity even in minute amounts. Since serious side effects can be triggered by endotoxin contamination of injectable pharmaceuticals, biological products, or medical devices, they must be rigorously controlled, especially in directly administered injectable treatments.

What are glucans?

(1→3)-β-D-glucans are structural components of the cell walls of fungi, as typified by molds and yeasts. Measurement of the glucan concentration in blood is widely used in auxiliary diagnosis of deep fungal infections and judgment of the therapeutic effect of antifungal agents.

Endotoxin-detecting reagents and devices

■ ENDOSPECY®, TOXICOLOR®, PYROCHROME®, etc.

Endotoxin-detecting reagents are reagents that measure endotoxins. Made from limulus amebocyte lysate (LAL), a substance extracted from the blood cells of horseshoe crabs, these reagents are used in quality control of injectable pharmaceuticals, biological products, and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.



Endotoxin-detecting reagents

■ PyroSmart NextGen™

PyroSmart NextGen is an endotoxin-detecting reagent manufactured using genetic recombination technology without the use of blood harvested from horseshoe crabs. Seikagaku successfully developed the world's first product consisting of recombinant proteins of Factor C, Factor B, and a coagulating enzyme precursor, which are components of horseshoe crab blood cells. Subsequently, PyroSmart NextGen was developed jointly by Seikagaku and overseas subsidiary Associates of Cape Cod, Inc. and is currently sold in Japan, Europe, and the U.S.

■ Endotoxin-detecting Systems

Seikagaku provides a wide range of endotoxin-detecting solutions to meet customers' needs, such as fully automatic and simultaneous multi-analyte measurement.



Automatic endotoxin-detecting systems

Beta-glucan-detecting in vitro reagent

■ Fungitell®

Fungitell is an in vitro diagnostic reagent used in the selection of treatment methods for deep fungal infections and judgment of therapeutic effect. Fungitell was developed by Seikagaku Corporation as the first product of its kind in the world and it is manufactured and sold in markets outside Japan by Associates of Cape Cod, Inc.

Pharmaceuticals Business

The Pharmaceuticals business is Seikagaku Corporation's core business. Seikagaku manufactures and provides pharmaceuticals and medical devices made with GAG, as well as enzymes that act on GAG. GAG stands for glycosaminoglycans such as hyaluronic acid or chondroitin sulfate, the main ingredients in Seikagaku products. GAG is also a structural component of glycoconjugates. Seikagaku contributes to medical care in Japan and around the world by providing global-class high-quality products with its unique technologies.

Joint Function Improving Agents

■ ARTZ Dispo®, SUPARTZ FX®, VISCO-3®

ARTZ Dispo, a prefilled syringe product*1, is a multiple-injection version of ARTZ*2, a joint function improving agent containing hyaluronic acid as its main active pharmaceutical ingredient. Multiple injections administered directly into the joint cavity at weekly intervals are expected to reduce pain and inflammation. ARTZ Dispo has been approved and is supplied not only in Japan, but also in overseas markets including the U.S., Asia, and Europe.

*1 A kit with an injectable syringe that has to be filled with solution.
*2 Delisted from the NHI drug price standard on March 31, 2022.



ARTZ Dispo®



SUPARTZ FX®

■ JOYCLU®

JOYCLU is a joint function improving agent in which diclofenac (an anti-inflammatory drug) is chemically bound to hyaluronic acid. Improvement of symptoms of osteoarthritis of the knee joint and hip joint is expected from the administration of JOYCLU into the joint cavity once every four weeks. JOYCLU is the first joint function improvement agent in Japan indicated for the treatment of osteoarthritis of the hip joint.



JOYCLU®

■ Gel-One®, HyLink®

Originally developed for the U.S. market, Gel-One is an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis that contains cross-linked hyaluronate hydrogel as its main ingredient. Administration of only 3mL provides long-lasting benefits. Gel-One is currently sold in Italy and Taiwan under the brand name HyLink.



Gel-One®

Treatment for Lumbar Disc Herniation

■ HERNICORE®

HERNICORE, which contains condoliase as its active pharmaceutical ingredient, is Japan's first product used in the treatment of lumbar disc herniation (intradiscal enzyme injection therapy). When injected directly into the lumbar disc, it relieves pressures on the nerves caused by hernia, reducing pain, numbness, and tingling. It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection.



HERNICORE®

Ophthalmic Viscoelastic Devices (OVD)

■ OPEGAN®, SHELLGAN®, Sodium Hyaluronate 0.4 Ophthalmic Viscoelastic Preparation 1% SEIKAGAKU

The OPEGAN series of products allows the creation of appropriate intraocular space by viscoelastic properties of hyaluronic acid in cataract surgery. The product range includes seven types of different volumes and viscoelastic properties to meet specific treatment needs.



OPEGAN® series

Submucosal Injection Agent for Endoscopic Surgery

■ MucoUp®

MucoUp is an endoscopic surgical aid that utilizes the viscoelastic properties of hyaluronic acid. Injecting MucoUp into the submucosa beneath the lesion during the endoscopic resection of tumors in the gastrointestinal tract, such as the esophagus, stomach, and large intestine, creates a durable tissue uplift and provides improved procedural maneuverability and efficiency for ESD/EMR.



MucoUp®

Bulk Products

■ Sodium hyaluronate, sodium chondroitin sulfate

Based on our unique extraction and purification technology, we manufacture and sell high-quality, high-purity hyaluronic acid and chondroitin sulfate, which are mainly raw materials for pharmaceuticals and cosmetics.



Bulk products

Contract Development and Manufacturing Organization (CDMO)

■ CDMO services

Seikagaku provides services to pharmaceutical companies, including manufacturing of chemical synthetics and pharmaceutical products on a contract basis and manufacturing process development. Seikagaku entered this business by acquiring Dalton Chemical Laboratories, Inc. as a subsidiary in March 2020.

Message from the President & CEO



Seikagaku will continue contributing to healthy and fulfilling lives for people around the world through new drug development specialized in glycoscience.

President & CEO *Ken Mizutani*

Focus of the mid-term management plan

Seikagaku has formulated a mid-term management plan that positions the four-year period from fiscal 2022 to fiscal 2025 as “A period for achieving growth” and is implementing key measures set out in the plan.

The five key measures in the management plan are: 1) Maximize the product value of SI-6603 (treatment for lumbar disc herniation), 2) Accelerate R&D utilizing unique drug-discovery technologies, 3) Maintain and enhance the business value of joint function improving agents, 4) Construct a global production system, and 5) Expand the LAL business through recombinant technologies. By implementing these key measures, Seikagaku aims to cultivate the ability to maintain a constant growth trajectory and achieve record-high business results in the final year of the plan.

The following are some key topics related to progress in achieving the plan.

Biologics License Application (BLA) for SI-6603 (a treatment for lumbar disc herniation) accepted for filing

Maintaining a constant growth trajectory is an important theme in the management plan. The key to achieving this is to obtain regulatory approval in the U.S. for SI-6603 (a treatment for lumbar disc herniation) and introducing it in the market.

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment for lumbar disc herniation directly injected into the intervertebral disc. It has the characteristic of not requiring general anesthesia and being less invasive to patients than surgical treatment, and a single injection is expected to improve the symptoms of lumbar disc herniation. Since its introduction in the U.S. market will provide a new option for treatment of lumbar disc herniation, SI-6603 is expected to become a major growth driver for Seikagaku.

A BLA for SI-6603 has been accepted for filing by the U.S. Food and Drug Administration, which means that the formulation is now a step away from approval. Seikagaku will mount an all-out effort to obtain approval for SI-6603 by fully utilizing the Group’s overseas business sites, including Seikagaku North America Corporation (SNA), our North American development base.

In addition to this collaboration within the Group, Seikagaku is cooperating closely with Ferring Pharmaceuticals Inc., the local distributor, to establish a system that will enable sales to begin promptly after approval. The aim is to maximize product value by achieving rapid penetration into medical institutions.

Construction of a global production system

Canadian subsidiary Dalton Chemical Laboratories, Inc. (DCL) provides services to pharmaceutical companies, including the manufacturing of chemical synthetics and pharmaceutical products on a contract basis. Currently, we are proceeding with a switch to in-house production at DCL of chemical synthetics necessary for manufacturing Seikagaku products and the partial transfer of pharmaceutical ingredients manufacturing to DCL.

Under the current mid-term management plan, with a view to future business development, we are actively investing in facilities and reinforcing human resources to construct a system that will enable DCL to manufacture certain Seikagaku products, including new products. In addition, we have dispatched personnel from Seikagaku to SNA and are proceeding with the transfer of manufacturing technologies.

We will continue to make appropriate and active investments in pursuit of production optimization and efficiency improvement.

Expansion of the LAL business

The endotoxin-detecting reagents sold in the LAL business play an important role in quality control of pharmaceutical and medical device manufacturing processes.

We are steadily increasing sales of the gene-recombinant endotoxin-detecting reagent PyroSmart NextGen by gathering scientific data, increasing awareness through authoring of academic papers, and acquiring new customers. Also, we have increased the number of countries where Fungitell, the world’s first beta-glucan-detecting in vitro diagnostic test, is sold and entered the hospital market. Fungitell was developed by Seikagaku.

We will continue to collaborate with overseas subsidiary Associates of Cape Cod, Inc. to expand the LAL business by pursuing differentiation from competitors.







Sustainability initiatives

Seikagaku also regards the pursuit of sustainability as an important priority. We are devising and implementing effective measures based on the Basic Policy on Sustainability, instituted in 2021, and extending their scope of application to subsidiaries. These measures are focused on the six material issues that give concrete shape to the sustainability policy.

In fiscal 2023, we conducted an engagement survey of all employees as an aspect of "Promotion of diversity and development of human resources," one of the six material issues. Informed by the survey results, we will continue our efforts to create an environment in which large numbers of employees can fully demonstrate their capabilities and ensure that their contributions and successes are the driver of Seikagaku's sustained growth.

Also, as an activity related to "Engagement in environmentally friendly corporate activities," we have procured CO_2-free electricity and achieved conversion to non-fossil energy at four business sites in Japan. Going forward, we plan to install solar carports equipped with photovoltaic power generation facilities at the Takahagi Plant, and further CO_2 emissions reduction is expected.

These and other initiatives were positively evaluated by external assessment organizations. Seikagaku was awarded a Silver sustainability rating for 2023 by EcoVadis, a CDP climate change assessment score of B, and a Class S energy conservation performance assessment based on the Act on the Rational Use of Energy.

Seikagaku will continue to work toward the sustainable development of the Earth and society and strive to sustainably develop together with society.

Seikagaku has identified and is focusing on six material issues related to the following eleven Sustainable Development Goals (SDGs).
(For details, please refer to the section "Six Material Issues" beginning on Page 15.)



To our shareholders and other stakeholders

For more than 70 years, Seikagaku has operated in accordance with the management creed "Under the principle of respect for learning, we contribute to human well-being by creating and supplying the world with safe and useful pharmaceutical products based on glycoscience."

We are steadily proceeding with development in the U.S. of SI-6603, a treatment for lumbar disc herniation, mounting an all-out effort to provide suffering patients with a new treatment option as soon as possible.

For Seikagaku to deliver SI-6603 and other new medications to patients, the cooperation of diverse stakeholders is essential. I refer not only to medical practitioners and distributor employees, but Seikagaku employees and shareholders as well.

The operating environment facing pharmaceutical companies is becoming increasingly difficult each year. I request the continued understanding and support of our stakeholders to enable Seikagaku to continue to assist patients around the world to lead healthy and fulfilling lives.

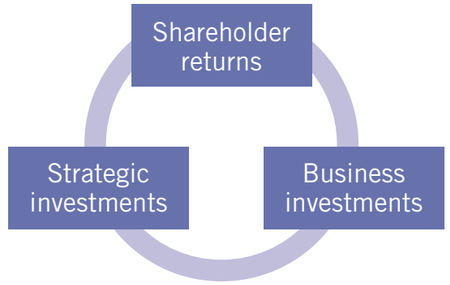
President & CEO



Basic policy on profit distribution

Seikagaku believes that sustained profit growth and enhancement of corporate value contribute to the common interests of the shareholders. Management regards the return of profits to shareholders as an important priority and, while taking an annual dividend of ¥26 per share as the basis, will consider dividend increases, taking into account the trend in business performance, the financial position, and other factors. Also, while taking into consideration future business expansion and the total return ratio, Seikagaku will consider the purchase of treasury stock when appropriate. Seikagaku plans to pay an annual dividend of ¥30 per share, including the interim dividend, for the fiscal year ending March 31, 2025.

In addition, in order to solidify the business foundation and improve capital efficiency, the Company will make efficient and active business investments in R&D for creating new value, in production system development, and in sustainable activities and will flexibly make strategic investments offering prospects for future growth and synergy effects.



Shareholder returns	• Consider dividend increases, while taking an annual dividend of ¥26 per share as the basis, taking into account business performance and other factors. • Consider the purchase of treasury stock when appropriate.
Business investments	• Continue efficient investments in R&D and production. • Make active business investments in sustainable activities.
Strategic investments	• Flexibly consider strategic investments with prospects for future growth and synergy effects.

	Forecast for Fiscal 2024	Fiscal 2023 Results
2nd Quarter	¥15.00	¥13.00
Fiscal Year-end	¥15.00	¥13.00
Annual Total Dividend	¥30.00	¥26.00
Dividend Payout Ratio	47.4%	64.9%

Value Creation

Innovating Novel Contributions and Approaches

As a company specializing in glycoscience, Seikagaku works to find solutions to social issues, increase its corporate value, and contribute to the health and well-being of humanity by creating novel and effective pharmaceuticals and medical devices and providing them to the world.

Social issues and the external environment

- Response to unmet needs
- Increased incidence of locomotive syndrome
- Super-aging society
- Increased healthcare access
- Declining probability of success in new drug development
- Protracted new drug development periods and soaring costs
- Contraction of the Japanese market, expansion of the global market
- Aggravation of environmental problems, environmental consideration (ESG), environmental conservation initiatives



Forms of capital advantageous for R&D and domestic and international alliances

Financial capital
- A stable financial base that provides the source of funds for continuous new drug creation

Manufacturing capital
- Manufacturing and quality management systems for the stable provision of high-quality pharmaceuticals

Intellectual capital
- Accumulated glycoscience-related chemical compound library
- Drug creation capabilities focused on target substances and high-priority target diseases

Human capital
- People capable of creating new value by applying a high level of expertise in a challenge-driven corporate culture

Social capital
- Relationships of trust with stakeholders for realization of a sustainable society

Natural capital
- Low-environmental-impact business activities as a life sciences company
- Corporate management that gives consideration to biodiversity

An original business model of specializing in R&D and manufacturing

Specialization in R&D and manufacturing
- Lean organizational structure with no pharmaceutical marketing units
- R&D investment equivalent to 20–30% of net sales



State-of-the-art technology related to GAG
- Advanced manufacturing basic technologies, including extraction, purification, cultivation, fermentation, and other technologies
- The ability to create diverse new pharmaceuticals based on the use of GAG and related enzymes

Mid-term management plan

Ⅰ Maximize the product value of SI-6603 (treatment for lumbar disc herniation)

Ⅱ Accelerate R&D utilizing unique drug-discovery technologies

Ⅲ Maintain and enhance the business value of joint function improving agents

Ⅳ Construct a global production system

Ⅴ Expand the LAL business through recombinant technologies

P17

Output

Provision of innovative, high-quality pharmaceuticals and medical devices, etc.
- Ethical pharmaceuticals, medical devices
- Bulk products
- CDMO services (contract development and manufacturing)
- LAL-related products

P07



Business flow

R&D	Production	Marketing (through sales partners)
P21	P31	P29
Quality compliance		
P27		

Material issues

1. Creation of truly useful pharmaceuticals and medical devices
2. Provision of a stable supply of pharmaceuticals and medical devices of guaranteed quality
3. Expansion of healthcare access and appropriate provision of high-quality medical information
4. Fair and ethical business activities and strengthening of corporate governance
5. Promotion of diversity and development of human resources
6. Engagement in environmentally friendly corporate activities


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Creation of economic value and social value

Medical institutions and patients
- Contribution to QOL improvement
- Creation of truly useful pharmaceuticals
- Provision of a stable supply of pharmaceuticals and other products of guaranteed quality

Shareholders
- Stable shareholder returns provided through sustained growth
- Fair information provision
- Enhancement of shareholder value

Employees
- Provision of growth opportunities
- Provision of an environment, systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities

Society
- Contribution to realization of a sustainable society
- Further development and refinement of glycoscience research technologies



Resolution of social issues and actualization of the management philosophy

Glycoscience for Human Well-being

Six Material Issues

Seikagaku Corporation has identified six material issues on the basis of assessment of important issues that should be addressed on a priority basis in the interest of achieving sustainable development of society and enhancement of corporate value, in light of both their importance to the Company and the expectations of society, including diverse stakeholders. By promoting initiatives related to these material issues, Seikagaku will contribute to achievement of the Sustainable Development Goals (SDGs) adopted by the United Nations.

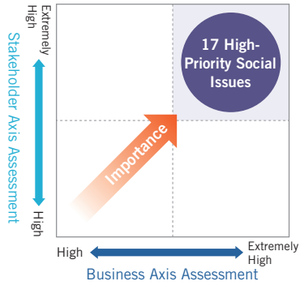
Material Issue Identification Process

Step 1 Identification and organization of social issues

To identify material issues, we identified social issues based on factors including non-financial information disclosure guidelines; international frameworks, principles, and guidelines; and survey items from ESG assessment organizations. Furthermore, we closely examined issues specific to the pharmaceutical industry. On that basis, we compiled a list of 39 social issues.

Step 2 Prioritization of social issues

Using the list of 39 social issues identified in Step 1, we assessed the importance of issues to Seikagaku in light of its Corporate Philosophy, management strategies, and financial situation. Also, an external consultant scored, analyzed, and organized the issues from an outside perspective to assess the expectations of society, including diverse stakeholders. Based on the results of this assessment process, we prepared a social issues assessment matrix and shortlisted 17 high-priority social issues of importance to both Seikagaku and society.



Step 3 Identification of material issues through validation and grouping of issues

To validate the social issues assessment matrix prepared in Step 2, following discussion and careful examination of the matrix together with involved Seikagaku divisions and departments and an external consultant, the Board performed grouping of the 17 high-priority social issues and identified six material issues relevant to Seikagaku. The Board articulated reasons for selection and a future vision and determined objectives, initiatives, and monitoring indicators for each identified material issue and organized and confirmed their relevance to SDGs. The material issues were then deliberated and approved by the Board.

Material Issues

Material Issues	Future Vision	Results (Fiscal 2023)*1
1 Creation of truly useful pharmaceuticals and medical devices	Seikagaku increases its value to society by utilizing knowledge of glycoscience to continuously create pharmaceuticals and medical devices that are truly needed by society, and contribute to the health and well-being of people around the world. Seikagaku also considers intellectual property to be an important management resource and implements a global intellectual property strategy to contribute to the continuous creation of pharmaceuticals and medical devices. **R&D P21**	■ Achieved primary endpoints for Phase III clinical study for SI-6603 in the U.S. and pivotal study for SI-449 in Japan ■ Completed approval filing for SI-6603 with the U.S. FDA ■ Promoted creation of new research themes in disease areas with high unmet medical needs
2 Provision of a stable supply of pharmaceuticals and medical devices of guaranteed quality	Seikagaku strengthens its compliance and production systems to ensure uninterrupted access to reliable pharmaceuticals and medical devices for patients and medical institutions. Also, we manage risks associated with raw materials procurement and other business processes and take all possible measures to prevent risks from materializing. **Quality compliance P27** **Production P31**	■ Conducted 22 audits (paper and on-site) of contract manufacturers, suppliers, and distributors ■ Underwent regular audits by authorities in Japan and abroad. No serious issues noted. Addressed minor issues and guidance items ■ Confirmed GMP compliance and development of a quality culture through periodic management reviews ■ Adopted performance indicators on each plant basis to foster culture of quality ■ Identified issues in system building to achieve more sophisticated inventory control
3 Expansion of healthcare access and appropriate provision of high-quality medical information	Seikagaku promotes global distribution of pharmaceuticals and medical devices that address medical needs and, as a pharmaceutical manufacturer, strives to enhance information provision in order to achieve appropriate awareness of the safety and efficacy of our pharmaceuticals and medical devices and of diseases related to our products. **Marketing P29**	■ Published three research papers and gave two academic presentations as part of evidence generation leading to drug fostering and evolution ■ Built new evidence with eight joint-research collaborations related to post-marketing product development ■ Held seminars and briefings in cooperation with sales companies and participated in exhibitions (16 co-sponsored seminars in Japan) ■ Participated in media interviews and shared information on our website to inform physicians and educate the public about the disease ■ Ran patient-focused campaigns in cooperation with sales companies
4 Fair and ethical business activities and strengthening of corporate governance	Seikagaku engages in business management to ensure that each employee not only complies with laws and regulations, but also behaves on the basis of high ethical standards. Seikagaku also continuously works to develop a highly effective corporate governance system. **Corporate governance P41** **Compliance and risk management P51**	■ Expanded the scope of application of sustainability-related polices to subsidiaries ■ Made partial revisions to the SKK Group Compliance Code of Conduct (expanded provision concerning respect of human rights) ■ Made partial revisions to compliance-related rules (added provision for establishing third-party committees for serious matters) ■ Conducted Code of Conduct training, theme-based training, and an awareness survey to foster an awareness of compliance ■ Held meetings with outside directors concerning initiatives for human capital management
5 Promotion of diversity and development of human resources	Seikagaku considers human resources to be an important corporate asset and works to develop people capable of creating new value. We develop an environment, systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities so that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth. **Social contribution activities P38** **Human resources P39**	■ Conducted an employee engagement survey ■ Shared a variety of human capital data in our disclosures, including information on growth opportunities and employment diversity ■ Made continuous improvements to the training curriculum and enhanced feedback to managers about workers' training status ■ Adopted a working system and compensation designed to support increased production at plants and a stronger foundation, and enhanced recruiting ■ Decided on in-house seminars in light of stress check results as part of efforts to promote employee health
6 Engagement in environmentally friendly corporate activities	As a member of society, Seikagaku aims to achieve balance between environmental protection measures and business growth and engages in business activities with low environmental impact in addition to obeying environment-related laws and regulations. **Basic Policy on Sustainability P34** **Information disclosure based on the TCFD recommendations P35** **Initiatives for biodiversity P37**	■ Achieved continuous reduction in energy use (five-year average energy consumption rate of 97.5% / energy conservation evaluation*2: Class S) ■ Achieved a reduction in CO_2 emissions (6.0% reduction from the previous year) ■ Procured CO_2-free electricity, successfully switching to non-fossil fuel energy at four sites in Japan ■ Continued horseshoe crab release and conservation activities at a group company

*1 Results for fiscal 2023 and beyond are partly included.
*2 Business operators are classified according to their energy conservation results as Class S (superior energy conservation performance), Class A (average energy conservation performance), or Class B (energy conservation not progressing). Class S business operators are recognized on the Ministry of Economy, Trade, and Industry website as excellent business operators.

Please see here for more details on materiality.
https://www.seikagaku.co.jp/en/sustainability/materiality.html

Mid-term Management Plan FY2022 to FY2025

Seikagaku has positioned the four-year period beginning with the fiscal year ended March 31, 2023 (fiscal 2022) as “A period for achieving growth” and formulated a new mid-term management plan. By implementing key measures set out in the plan, based on a solid profit foundation established during the previous management plan, Seikagaku will aim to maintain a constant growth trajectory and achieve record-high business results in the final year of the plan.



<Assumptions>

- U.S. market introduction of SI-6603 (treatment for lumbar disc herniation)
- Profit expansion from joint function improving agents in Japan
- Expansion of the overseas pharmaceutical and LAL business
- Ratio of R&D expenses to sales (excluding royalty income): target of 25%
- Exchange rate: ¥135/US$1

Overview of Key Measures

Seikagaku has been implementing the five key measures in the management plan to develop the ability to maintain a constant growth trajectory.

In addition, enhancement of employee engagement along with organizational strengthening and human resource development will be critical factors for carrying out the above five key measures. Seikagaku will work to solidify and improve the foundation for achieving sustained growth by stepping up investment to create an environment that promotes development and growth of human resources, the heart and soul of the Group’s businesses.

Ⅰ	Ⅱ	Ⅲ	Ⅳ	Ⅴ
Maximize the product value of SI-6603 (treatment for lumbar disc herniation)	Accelerate R&D utilizing unique drug-discovery technologies	Maintain and enhance the business value of joint function improving agents	Construct a global production system	Expand the LAL business through recombinant technologies
P18	P18	P19	P20	P20

Business foundation

Enhancement of employee engagement/
Organizational strengthening and human resource development

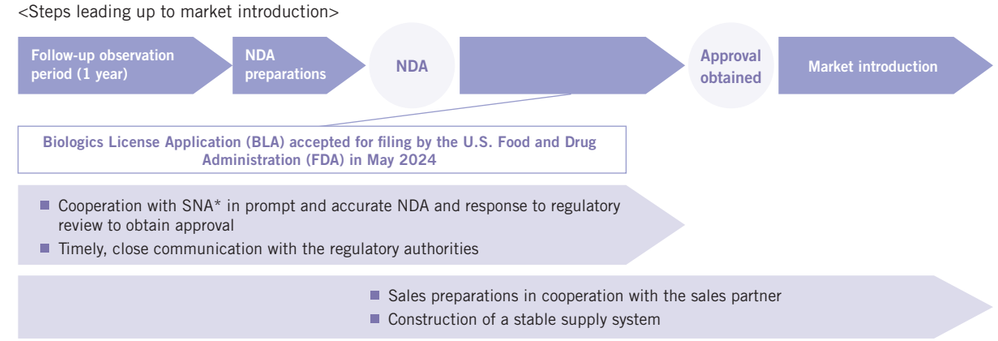
Summary of the Key Measures

Ⅰ Maximize the Product Value of SI-6603 (treatment for lumbar disc herniation)

Aim for an NDA, approval, and market introduction during the period of the mid-term management plan.

Ensure a prompt and accurate NDA and response to regulatory review in order to obtain approval in the U.S. and launch SI-6603, a treatment for lumbar disc herniation. Also proceed with sales preparations and pursue maximization of product value through early penetration at medical institutions in close cooperation with the sales partner. (For information on the development status and characteristics of SI-6603, please refer to the section “Research and Development” beginning on page 21.)

<Steps leading up to market introduction>



State of progress

- BLA, submitted in March 2024, accepted for filing by the FDA (May 2024)
- Preparations underway for launch in the final year of the mid-term management plan, as originally planned

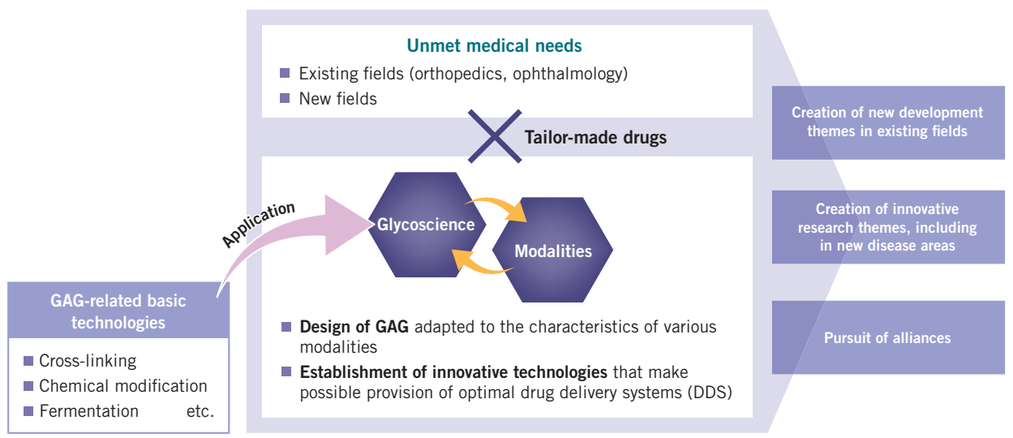
* SEIKAGAKU NORTH AMERICA CORPORATION

Ⅱ Accelerate R&D Utilizing Unique Drug-discovery Technologies

Create products that patients need utilizing Seikagaku’s own GAG-related technologies and aim for steady advancement of the pipeline list.

Apply Seikagaku’s own GAG*-related basic technologies to create new drugs that patients truly need, with an emphasis on unmet medical needs, by focusing on creation of new development themes in existing fields and creation of innovative research themes, including in new disease areas. Also, to increase the probability of success of these efforts, pursue various alliances aimed at making early progress.

* GAG: Glycosaminoglycans, such as hyaluronic acid and chondroitin sulfate, which are structural components known as glycoconjugates.



Pipeline List (Research and Development themes)

Advance existing pipelines with the aim of obtaining approval and introducing in the U.S. SI-6603 (a treatment for lumbar disc herniation), completing a Phase III clinical study in the U.S. of SI-614 (a treatment for dry eye), and obtaining approval in Japan and initiating a clinical study in the U.S. of SI-449 (an adhesion barrier).

[Pharmaceuticals]

(As of September 30, 2024)

Development code/Product name		Indication	Developed in	Phase I	Phase II	Phase III	Application	Market approval
SI-6603	Condoliase	Lumbar disk herniation	USA				⇨	
SI-614	Modified Hyaluronate	Dry eye	USA			⇨		
SI-613	Diclofenac etalhyaluronate sodium	Knee osteoarthritis	USA					
SI-613-ETP	Diclofenac etalhyaluronate sodium	Enthesopathy	Japan		Phase I/II b (Discontinued (February 2022))			
SI-722	Steroid compound sodium chondroitin sulfate	Interstitial cystitis and bladder pain syndrome	USA		Phase I/II			

[Medical Devices]

Development code/Product name		Description	Developed in	Pilot study	Pivotal study	Application	Market approval
SI-449	Cross-linked Chondroitin Sulfate	Adhesion barrier	Japan			⇨	
SI-449	Cross-linked Chondroitin Sulfate	Adhesion barrier	USA				

⇨ Planned progress as of the end of fiscal 2025

State of progress

- SI-6603 (treatment for lumbar disc herniation): Proceeding with efforts to obtain approval (as described in Section I)
- SI-449 (adhesion barrier): Results showing statistically significant improvement in both the primary endpoint and secondary endpoints obtained in a pivotal study being conducted in Japan (July 2023)
- SI-614 (treatment for dry eye): Considering the future development policy in light of the absence of results indicating statistically significant improvement in the primary endpoint in a Phase III clinical study in the U.S.

Ⅲ Maintain and Enhance the Business Value of Joint Function Improving Agents

Seek to enhance business value through maximization of Seikagaku products in the market for joint function improving agents and cost structure improvement.

Strive to maintain and enhance the business potential of the core products that support business management by increasing the presence of Seikagaku products in the mainstay domestic market for joint function improving agents. Since the domestic pharmaceuticals business is greatly affected by NHI drug price reductions, cost structure improvement is essential. Seikagaku will further proceed with product material specification changes, which help ensure continuity of product supply, manufacturing process efficiency improvement, and other measures. Seikagaku will also continue gathering and providing safety information on the joint function improving agent JOYCLU with the aim of contributing to appropriate prescription on the basis of clinical research findings.

Maximization of Seikagaku products in the market for joint function improving agents

×

Cost structure improvement

▼

Maintenance and enhancement of business value that supports business management

State of progress

- Proceeding with production system expansion and a change of product materials for the purpose of further cost structure improvement due to a rapid market share increase for ARTZ
- Continued to gather and provide safety information on JOYCLU and conducted clinical research

Ⅳ Construct a Global Production System

Undertake construction of a global production system with Japan and North America as dual production bases, including transfer of production of some products.

Further reinforce a stable supply of products on the basis of an appropriate and efficient production system by making Dalton Chemical Laboratories, Inc. (DCL) and the Seikagaku Takahagi Plant dual production bases.



Seikagaku Corporation Takahagi Plant
(Ibaraki Prefecture, Japan)

▶ Please refer to “Overview of Domestic Production Sites” on page 31.



DALTON CHEMICAL LABORATORIES, INC.
(Toronto, Canada)

▶ Please refer to “Overseas Subsidiaries” on page 58.

State of progress

- Proceeding with construction of a manufacturing system at DCL to create dual formulation sites

Ⅴ Expand the LAL Business Through Recombinant Technologies

Accomplish a transformation necessary from a long-term perspective in addition to continuation of current businesses and product improvement.

Further reinforce a stable supply of products on the basis of an appropriate and efficient production system by making DCL and the Seikagaku Takahagi Plant (Ibaraki Prefecture, Japan) dual production bases, including transfer of production of some products.

▶ Please refer to “Overseas Subsidiaries” on page 58.



Endotoxin-detecting reagent
PyroSmart NextGen®

State of progress

- Continued gathering scientific data relating to PyroSmart NextGen (a recombinant LAL reagent) and co-authoring of academic papers with ACC
- Increased the number of countries where Fungitell (a beta-glucan-detecting in vitro diagnostic test) is sold and entered the hospital market

For details on the mid-term management plan:

https://www.seikagaku.co.jp/en/ir/management/midtermplan.html

Research and Development

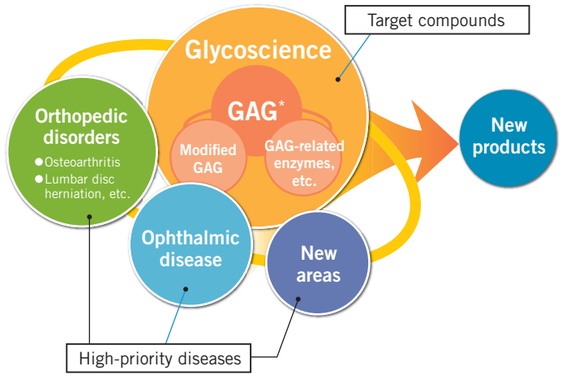
Seikagaku engages in research and development of innovative drugs in our specialty field of glycoscience. And we contribute to the health and well-being of people around the world.



R&D policy

In order to rapidly and continuously create new products, Seikagaku engages in efficient R&D activities by focusing on target compounds and prioritizing target diseases. The focus of our drug discovery is glycosaminoglycans (GAG), which are the structural components known as glycoconjugates.

In research spanning nearly 70 years, we have accumulated a wealth of experience and expertise related to GAG drug discovery research and GAG production and formulation technologies. Today, we apply hyaluronic acid or unmodified GAG in pharmaceuticals and also engage in research and development of modified GAG produced using a cross-linking technology as well as enzymes and other substances that act on GAG. Given the properties of GAG, we focus mainly on orthopedic disorders and ophthalmic diseases as high-priority areas for now, where we have expertise through the development of such products as ARTZ Dispo joint function improving agent and OPEGAN ophthalmic viscoelastic device.



*GAG: Glycosaminoglycans
(One of the constituents of complex carbohydrates)

Direction of R&D and future drug discovery approach

Seikagaku possesses a GAG compound library, GAG-related enzymes, and wide-ranging technologies for manipulating these substances. We actively utilize these assets, accumulated in the course of research spanning many years, in drug discovery activities. We have also developed a global network of collaborating glycoscience researchers and engage in multiple joint research projects with universities and research institutes.

Specifically, we continue to focus on drug discovery for orthopedic disorders and ophthalmic diseases and have also begun utilizing GAG-related technology to expand new fields. At the same time, we make efforts to maximize the value of our products on the market or themes in development through expansion of indications, additional formulations, changes in dosage and administration, etc.

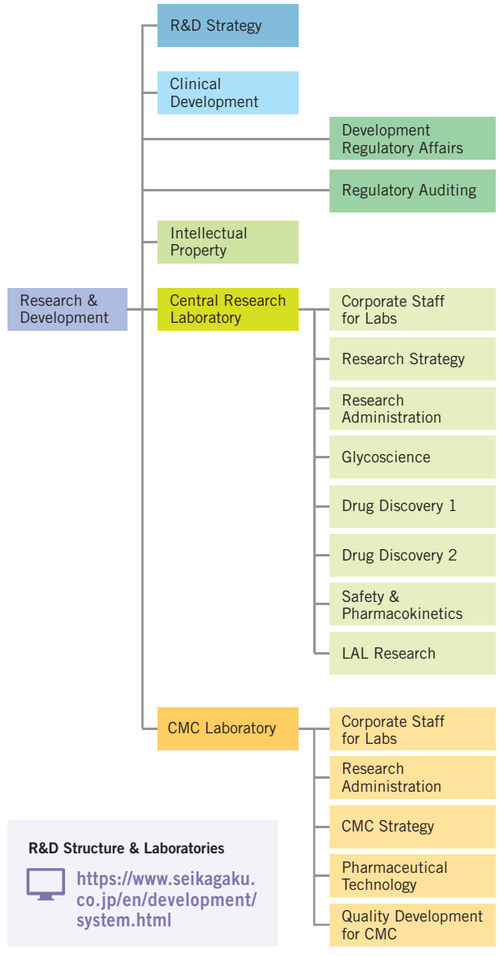
Until now, Seikagaku has followed a drug discovery approach of increasing the bioactivity of GAG, mainly through GAG modification and processing, and we are currently applying GAG to drug delivery systems (DDSs). Furthermore, going forward, we will also adopt an approach focused on the biological functions of sugar chains to open up new possibilities in drug discovery.

In our DDS, we are researching technologies that utilize the characteristics of modified GAG to freely control drug dose and the location and timing of release. We will pursue drug discovery and development capable of responding to a wide range of unmet medical needs by designing GAG for various modalities—not only low-molecular compounds, but also so-called middle molecules, such as peptides and nucleic acids, and high polymers, such as proteins—and providing Seikagaku's own DDS.

Research and development organization

To ensure close coordination of the drug development process from its upstream to downstream, Seikagaku has put in place an organizational structure in which the departments involved in R&D are consolidated under the control of the Research & Development Division. This integrated organization covers every R&D activity from clinical development to new drug application (NDA) and intellectual property strategy. In this structure, the Central Research Laboratory is in charge of exploring candidate substances and evaluating efficacy, safety, and pharmacokinetics, and the CMC Laboratory is responsible for production of investigational drugs, design of manufacturing processes, and consideration of commercial production.

[Research & Development Division Structure]
(As of July 1, 2024)



R&D Structure & Laboratories
https://www.seikagaku.co.jp/en/development/system.html

Drug discovery research

The Central Research Laboratory, Seikagaku's drug discovery research center, cultivates the creativity of researchers in a fulfilling research environment, equipped with advanced facilities, and places importance on fostering a self-help culture.

Seikagaku contributes unique knowledge, technology, and expertise related to glycoscience to benefit drug discovery research, and actively collaborates with universities and companies in Japan and overseas to accelerate the search for ideas and development of new technologies. Through these efforts, we work to create original pharmaceuticals and medical devices on the basis of specialized technologies and creative ideas.

[Overview of Research Units]
Glycoscience: Exploration of GAG (glycosaminoglycans) and related compounds as pharmaceutical candidate substances
Drug Discovery: Synthesis of new candidate substances with GAG as the basis for research, evaluation of their efficacy and function, and research on their actions and mechanisms
Safety & Pharmacokinetics: Evaluation of pharmacokinetics and toxicity profiles of candidate substances in vivo
LAL Research: Development of manufacturing technologies for reagents and diagnostics based on exploratory research of new technologies

CMC research

The CMC Laboratory produces investigational drugs, designs manufacturing processes, engages in quality development, and examines commercial production of products under development created by the Central Research Laboratory. By engaging in development from the R&D stage in collaboration with the Production Division, the CMC Laboratory aims to ensure the stable supply of high-quality pharmaceuticals and medical devices that comply with regulations in Japan, the United States, and Europe and to increase the speed of new drug development under a system integrated from research to production.

[Overview of Research Units]
Pharmaceutical Technology: Design of active pharmaceutical ingredients, pharmaceutical formulations, packaging, and manufacturing processes for candidate substances and consideration of commercial production
Quality Development for CMC: Research of physicochemical properties, development of testing methods for quality evaluation, and quality assurance of investigational drugs

Research and Development

Development Pipeline

[Pharmaceuticals]

(As of September 30, 2024)

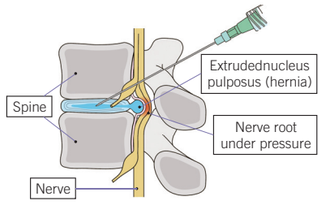
Development code/Product name		Indication	Developed in	Phase I	Phase II	Phase III	Application	Market approval
SI-6603	Condoliase	Lumbar disk herniation	USA				■	
SI-614	Modified Hyaluronate	Dry eye	USA			■		
SI-613	Diclofenac etalhyaluronate sodium	Knee osteoarthritis	USA		■			
SI-613-ETP	Diclofenac etalhyaluronate sodium	Enthesopathy	Japan		Phase IIb (Discontinued (February 2022))			
SI-722	Steroid compound sodium chondroitin sulfate	Interstitial cystitis and bladder pain syndrome	USA		Phase I/II			

[Medical Devices]

Development code/Product name		Description	Developed in	Pilot study	Pivotal study	Application	Market approval
SI-449	Cross-linked Chondroitin Sulfate	Adhesion barrier	Japan		■		

SI-6603 (treatment for lumbar disc herniation)

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment for lumbar disc herniation directly injected into the intervertebral disc. It has the special characteristic of not requiring general anesthesia and being less invasive to patients than surgical treatment. Since a single injection is expected to improve the symptoms of lumbar disc herniation by reducing intervertebral disc pressure and relieving pressure on the nerve root, SI-6603 can contribute to improving patients' quality of life as a new treatment option.



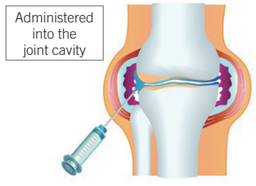
Administration of SI-6603

In Japan, marketing approval was obtained from the Ministry of Health, Labour and Welfare in March 2018, and SI-6603 was launched on August 1, 2018 as HERNICORE 1.25 units for intradiscal injection.

In the U.S., a Biologics License Application for SI-6603 was submitted in March 2024 and accepted for filing by the U.S. Food and Drug Administration in May. Seikagaku is currently proceeding with a response to regulatory review to obtain approval.

SI-613 (treatment for osteoarthritis)/SI-613-ETP (treatment for enthesopathy)

SI-613 is a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound using a drug binding technology proprietary to Seikagaku. By releasing diclofenac through hydrolysis, relief for osteoarthritis and enthesopathy can be expected.



Administration of SI-613

In Japan, marketing approval was obtained for SI-613 for its efficacy and effect on osteoarthritis (knee joint and hip joint) on March 23, 2021, and it was launched as joint function improvement agent JOYCLU® 30mg Intra-articular Injection in May of the same year. It is the first joint function improving agent in Japan indicated for osteoarthritis.

Since shock or anaphylaxis has occurred in Japan, to promote appropriate use, Seikagaku conducted clinical research to identify the cause of the side effects. Seikagaku will analyze data obtained through this research and continuously consider proposals that will lead to correct use.

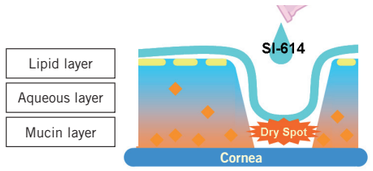
Seikagaku will consider the future direction for development in the U.S., China, and South Korea while assessing progress with identification of the cause of shock or anaphylaxis associated with JOYCLU in Japan.

The primary efficacy endpoint in a late-stage Phase II clinical trial in Japan of SI-613-ETP for the treatment enthesopathy was not met, and Seikagaku will prioritize identification of the cause of shock or anaphylaxis. For these reasons, development of SI-613-ETP was discontinued in February 2022.

SI-614 (treatment for dry eye)

SI-614, an ophthalmic solution, is a modified hyaluronate produced using Seikagaku's proprietary technology.

Instilling this solution as an eyewash is expected to improve dry eye symptoms by stabilizing the tear film and promoting corneal wound healing.

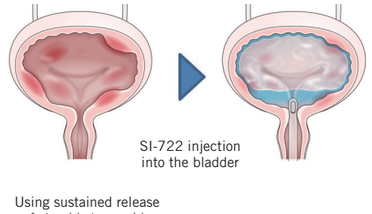


Administration of SI-614

Follow-up observation was completed in a Phase III clinical study in the U.S. with the objective of evaluating efficacy and safety in June 2023, and statistically significant improvement in the primary endpoint of the study was not observed. In light of this outcome, Seikagaku is considering the future development policy while proceeding with analysis of the data obtained.

SI-722 (treatment for interstitial cystitis and bladder pain syndrome)

SI-722 is a novel chemical compound in which a steroid is conjugated with chondroitin sulfate using Seikagaku's proprietary glycosaminoglycan modification technology and drug delivery systems. SI-722 injected into the bladder is thought to demonstrate an improvement effect in symptoms such as of frequent urination and bladder pain, by releasing a steroid with an anti-inflammatory effect.

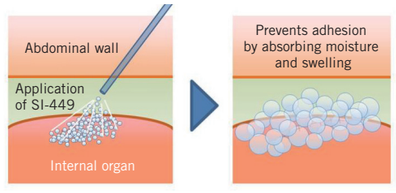


Administration of SI-722

While a Phase I/II clinical trial in the U.S. experienced delays in the trial schedule due to the spread of COVID-19, subject enrollment was completed in January 2021, and tolerability in the patients of this trial has been confirmed. Currently, we are exploring the next phase of trials based on the data we have obtained.

SI-449 (adhesion barrier)

SI-449 is a powdered adhesion barrier whose main ingredient is cross-linked chondroitin sulfate developed using Seikagaku's own glycosaminoglycan cross-linking technology. SI-449, which has the property of absorbing moisture and swelling, is expected to prevent or mitigate post-operative adhesion formation by forming a barrier between the surgical wound site and surrounding tissues after application. Development of this subject is progressing with an eye not only on domestic development, but also globally.



Use of SI-449

Follow-up observation in a pivotal study in Japan was completed in June 2023, and topline results showing statistically significant improvement in the primary endpoint and secondary endpoints of the study were obtained in July. In light of the results, together with the outcome of a pilot study in the field of gynecology, Seikagaku will proceed with preparations for an NDA at an early date.

Research and Development

The clinical study process and paths of new drug development

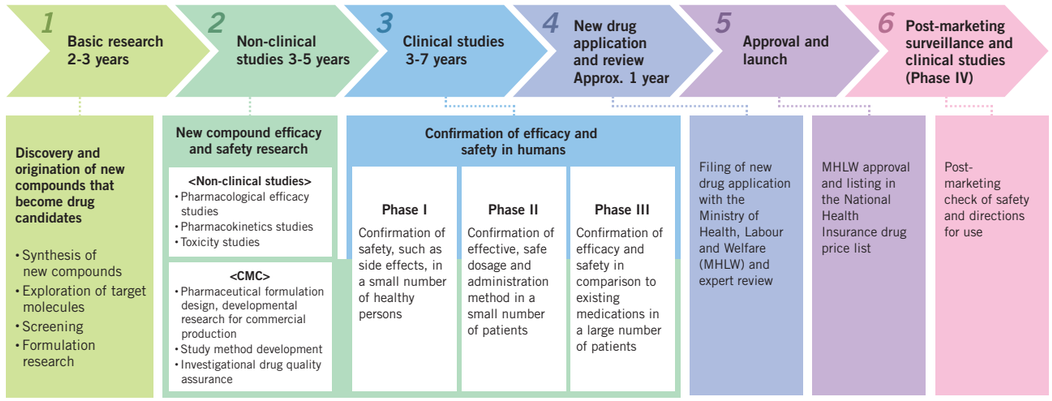
To create new drugs, it is necessary to conduct various studies to evaluate efficacy and safety. Clinical studies are conducted to confirm whether drug candidates are actually beneficial to humans, following completion of research processes such as basic research and non-clinical studies.

Clinical studies are ordinarily divided into three phases and conducted at medical institutions such as hospitals in conformance with rigorous standards after the consent of subjects (healthy persons or patients) has been obtained.

A Phase I clinical study, the initial phase, is ordinarily conducted for the main purpose of examining the pharmacokinetics (absorption, distribution, metabolism, and excretion) and safety (adverse events and side effects) of investigational drugs in a small number of healthy subjects. A Phase II clinical study examines efficacy, safety, and pharmacokinetics and confirms optimal dosage and usage in a small number of patients. A Phase III clinical study, the final phase, objectively verifies efficacy and safety in comparison to existing approved drugs or placebos in large numbers of patients.

Ordinarily, more than ten years is required from discovery of a candidate substance until its approval as a new drug. Within the long, difficult new drug development process, clinical development is considered to hold the key to whether an NDA can be filed.

[The Drug Research and Development Process]



Intellectual property strategy Involvement in various processes ranging from basic research to NDA

TOPICS

The TATENO Forum nurtures seeds that grow into new drugs

The TATENO Forum is a Seikagaku internal presentation forum held each year at the Central Research Laboratory for the purpose of sharing research results relating to new ideas and technology creation. Researchers from the Laboratory, as well as employees assigned to other business sites, actively take part in the forum, giving oral and poster presentations on numerous research themes and actively discussing their future potential and contribution to medical needs. Through the TATENO Forum, Seikagaku is focusing on generating candidate substances for future development by further refining new ideas through open discussion.

Seikagaku will continue efforts to expedite the creation of development themes, such as new pharmaceuticals that people truly need, by enhancing the company's R&D and technological capabilities through deepening of discussion and information sharing among employees.

*The forum name was taken from the location of the Central Research Laboratory (Tateno, Higashiyamato City, Tokyo).


Oral presentation


Poster presentation

Seikagaku and glycoscience

Seikagaku's Management Creed states: "We create safe and useful products for human well-being with basic research based on glycoscience." In keeping with this creed, we have made glycoscience the core foundation of our business and explicitly adopted a stance of respect for learning. Seikagaku's origin is closely bound up with this creed.

In 1950, Seikagaku became the first company in the world to successfully produce chondroitin sulfate, which is a sort of GAG, on a commercial scale. This breakthrough laid the foundation for our current business, which is centered on glycoscience. The manufacture of chondroitin sulfate marked the starting point for expansion of our business to bulk products, as well as reagents and diagnostics, and this has led to the strengthening of our ties to glycoscience-related academia and research institutes.

Through this close relationship with academia, we acquired the idea of applying hyaluronic acid in pharmaceuticals. R&D activities spanning many years culminated with the successful development and launch of ARTZ, the world's first joint function improving agent whose main ingredient is hyaluronic acid. The development of HERNICORE, a treatment for lumbar disc herniation that contains condoliase, an enzyme that degrades GAG, also originated from collaboration with academia.

Seikagaku will continue to make glycoscience the central focus of R&D activities and, on the basis of research results in the field of glycoscience achieved in collaboration with universities and research institutes, strive to create pharmaceuticals and medical devices and deliver them to patients around the world.

The difficulty of applying glycoconjugates to pharmaceuticals

GAG are formed when amino sugars (sugars that include nitrogen atoms) and uronic acids (a class of sugar acids) or galactose are linked together to form chain-like structures (sugar chains). Sugar chains are known in the life sciences as the third biological chain, along with nucleic acids and proteins, but they have complex chemical structures because they are molecules that handle various kinds of information within living organisms. In research in areas such as structural analysis, automatic synthesis, and large-scale synthesis, this complexity poses characteristic difficulties not found in other biological materials.

However, long-term efforts in the industry and academia have advanced the structural analysis and synthesizing technologies of sugar chains. In addition, the genes of sugar-chain synthesizing enzymes and degrading enzymes have been comprehensively identified, and our understanding of the homeostasis of sugar chains in living organisms and their pathological function is advancing. This progress in glycoscience technologies is closely linked with Seikagaku's drug discovery research.

Intellectual property strategy

Appropriate protection of intellectual property relating to Seikagaku's technologies, products, and other assets is essential not only for maintaining corporate competitiveness, but also for continuing to create and supply unique, high-quality pharmaceuticals and medical devices. Seikagaku views intellectual property as an important management resource and engages in global intellectual property-related activities.

The Intellectual Property Department engages in activities related to acquisition of intellectual property rights (patents, designs, trademarks, copyright, know-how, etc.) and their protection. It works closely with the Research & Development Division involved in drug discovery as well as with the Business Development & Marketing Division, Production Division, and other relevant Company organizations.

Fair R&D activities

In the interest of conducting fair R&D activities, Seikagaku has established the Ethical Review Committee for Research Using Human Specimens and the Animal Experimentation Ethics Committee. Through comprehensive examination of the appropriateness of clinical studies and research using human specimens and animal experimentation in these committees, including ethical and scientific perspectives, Seikagaku strives to rigorously ensure ethical consideration in R&D activities.

Support for product value optimization and long-term post-marketing drug development

Seikagaku has established the Medical Affairs Unit to provide current scientific knowledge to external professionals. Scientific experts apply an ethical perspective, which aids medical progress by creating and disseminating medical evidence relating to disease information and products within Seikagaku's focus, such as orthopedic disorders and ophthalmic diseases.

Quality Compliance

Seikagaku's mission is to provide patients with a continuous supply of safe, beneficial, high-quality pharmaceuticals and medical devices. We have constructed corporate quality assurance and compliance systems in accordance with laws, regulations, and standards.



Quality compliance system

Seikagaku places quality first, from R&D to post-marketing, by complying with overseas pharmaceutical laws and regulations, including GxP* regulations and guidelines. In Japan, as a marketing authorization holder, Seikagaku operates a legal compliance system under the officer responsible for pharmaceutical matters (Responsible Officer) in accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act"). And, the general marketing compliance officer, quality assurance supervisor, and safety management supervisor oversee appropriate quality management and pharmacovigilance operations.
To reliably provide pharmaceuticals and medical devices to patients around the world, we will continue to operate in accordance with global standards.

* GxP stands for Good XXX Practice, a collective term for standards established to ensure the efficacy, safety, and quality of pharmaceuticals and medical devices from R&D to post-marketing.

Quality management system based on global standards

To provide a stable supply of high-quality pharmaceuticals and medical devices, in accordance with our Quality Policy, we have developed a world-class quality management system. At the development stage, we ensure reliability under Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) standards. To ensure compliance with laws and regulations and maintenance of quality assurance systems through the post-marketing stage, each year we systematically conduct self-inspections and internal audits to confirm the status of operation of the quality management system and promptly take corrective and preventive actions as necessary.

Seikagaku has obtained ISO 13485 certification for the development, manufacture, and distribution of sodium hyaluronate-based viscoelastic products for the treatment of osteoarthritis of the knee and periarthritis of the shoulder. We strictly maintain and control quality at all stages from product design and development to post-marketing in conformance with these manufacturing control and quality assurance systems.

ISO 13485 is an international standard for quality management systems established by the International Organization for Standardization (ISO) that prescribes requirements concerning the design, development, and manufacturing of medical devices. In Japan, ISO 13485 has been adopted as an ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostics.

Safety management

Sometimes side effects not observed in the development stage come to light after the launch of a new pharmaceutical product. In accordance with Good Vigilance Practice (GVP) standards, Seikagaku conducts post-marketing pharmacovigilance activities involving promptly and appropriately collecting, evaluating, and sharing feedback information on the side effects of pharmaceuticals prescribed at medical facilities. Through these activities, we prevent the expansion of side effects and promote safety assurance and appropriate use of new drugs.

[Laws and Regulations Governing Pharmaceuticals and Medical Devices]

Life cycle	1 Basic research	2 Development	3 NDA	4 Manufacturing, quality control, information provision, and product supply	5 Post-marketing
Laws and Regulations: Pharmaceuticals	• PMD Act • GLP	• PMD Act • GLP • GCP • GMP for investigational products	• PMD Act	• PMD Act • GMP • GQP	• PMD Act • GPSP • GVP
Laws and Regulations: Medical devices	• PMD Act • GLP	• PMD Act • GLP • GCP • QMS	• PMD Act	• PMD Act • QMS	• PMD Act • GPSP • GVP

- PMD (Pharmaceuticals and Medical Devices) Act
  Act on securing quality, efficacy, and safety of products including pharmaceuticals and medical devices
- GLP: Good Laboratory Practice
  Standards for conducting non-clinical studies on safety
- GCP: Good Clinical Practice
  Standards for conducting clinical studies
- GMP: Good Manufacturing Practice
  Standards for manufacturing control and quality control in pharmaceuticals
- GVP: Good Vigilance Practice
  Standards for post-marketing safety management of drugs, quasi-drugs, cosmetics and medical devices, and regenerative medicine products
- GQP: Good Quality Practice
  Standards for quality control of products
- GPSP: Good Post-marketing Study Practice
  Standards for conducting post-marketing surveys and studies on drugs
- QMS: Quality Management System
  Ordinance on standards for manufacturing control and quality control of medical devices and in vitro diagnostic reagents



Executive Vice President
Reliability Assurance
Toshiyuki Okada

Roles of the Quality Assurance Division

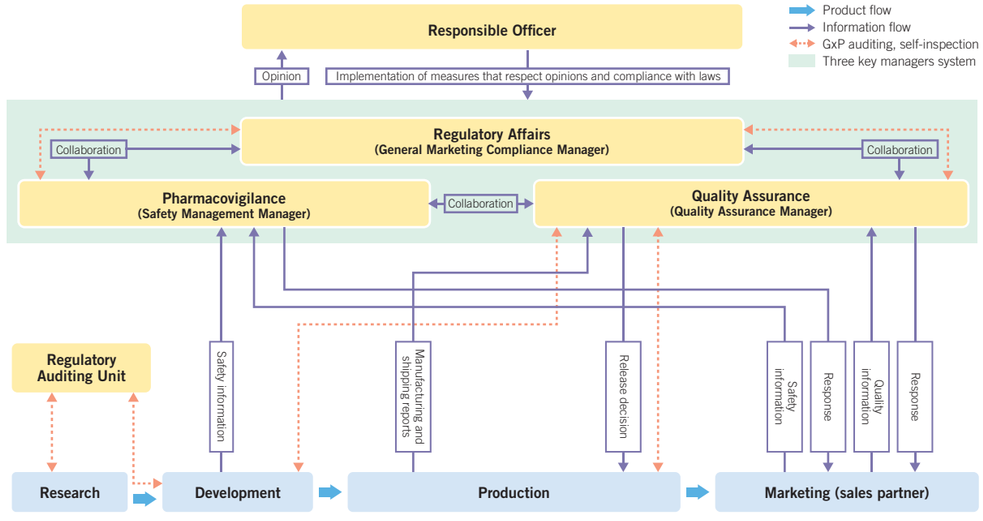
Although Seikagaku sells pharmaceuticals, medical devices, bulk products (hereafter collectively "products"), and measurement equipment and provides services in Japan and overseas, the Company believes that its greatest responsibility as a manufacturer is to continuously provide patients and medical practitioners with products of the same standard of quality as approved by the regulatory authorities. Specifically, this means observing product-related laws and regulations, manufacturing products that conform to standards using approved manufacturing methods, assuring efficacy and safety, and providing to medical practitioners without omission product information required by law, such as usage methods necessary for correct use, storage methods, expiration dates, and serial numbers.

It is also important to take measures to minimize risks by investigating whether safety risks are occurring either with respect to products themselves or to patients after use of products and by providing timely and appropriate information to medical institutions. At Seikagaku, this is the true function of Reliability Assurance, which is responsible for the serious business of protecting the safety and health of patients in our role as a pharmaceutical and medical device manufacturer.

The overseas sales ratio of Seikagaku products is increasing each year, and overseas sales have become an important pillar of Seikagaku's business. We are currently making preparations to obtain regulatory approval in the U.S. for a treatment for lumbar disc herniation, and the importance of our overseas business is likely to continue to increase in the coming years. Accordingly, in order to establish a global reliability assurance system, we are undertaking to correctly understand and comply with various laws and regulations specific to overseas markets and closely communicate with our local sales partners concerning product efficacy and safety information.

Reliability Assurance aims to establish a system that will enable us to continue to reliably fulfill our responsibilities as a manufacturer of pharmaceuticals and medical devices and will strive to maintain and improve product safety and reliability so that as many patients and medical practitioners as possible are able to correctly use products of the same high quality, wherever in the world they may be.

[Quality Compliance Structure]



Marketing

Seikagaku has a business model of supplying products through external partnerships in Japan and overseas in collaboration with pharmaceuticals and medical device sales companies. In this way, it intends to focus and develop its business activities without having an in-house pharmaceuticals sales division.



Pharmaceuticals and medical devices

To efficiently deliver these products to patients globally, Seikagaku forms partnerships with pharmaceutical companies that have expertise in each market, including Japan, rather than selling directly to pharmaceutical wholesalers and medical institutions. Through their activities, our partners, in conformance with laws and regulations on pharmaceutical sales, provide appropriate information on product efficacy, safety, quality, and other matters to physicians on a timely basis.

Seikagaku, in close cooperation with sales partners, formulates sales strategies, supports preparation of product information materials, analyzes the market environment, including information on competing products, and collaborates with academic societies. Through these activities, we support sales partner activities and appropriately promote market penetration for our products.

As part of product life cycle management, Seikagaku is implementing product modifications that respond to needs of a changing market. One example is the conversion of the material for syringes, used for the joint function improving agent ARTZ Dispo, from glass to plastic. Through these efforts, we are adding value to our products.

Furthermore, we have been accelerating overseas business expansion in recent years. We are working to increase sales in countries where we already do business, and to meet global medical needs, we are implementing a plan to introduce existing products and products in development into new markets.

Bulk products

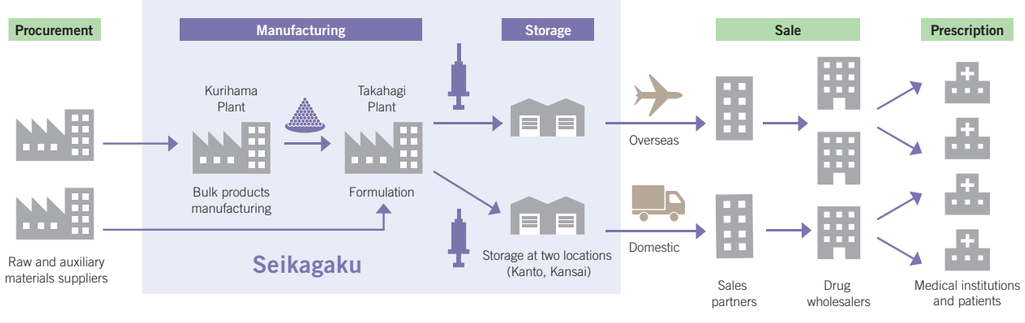
Using proprietary extraction and purification technologies, Seikagaku manufactures high-purity and high-quality hyaluronic acid and chondroitin sulfate and sells them to pharmaceutical and cosmetic companies, and others globally.

The bulk products are widely applied as active pharmaceutical ingredients for orthopedics and ophthalmology. In recent years, those bulk products are also being considered as new application materials in the regenerative medicine area.

Contract development and manufacturing organization (CDMO)

A contract development and manufacturing organization (CDMO) is a business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational drugs, and optimization of manufacturing conditions. In March 2020, we added to our business by acquiring Dalton Chemical Laboratories, Inc. as a subsidiary.

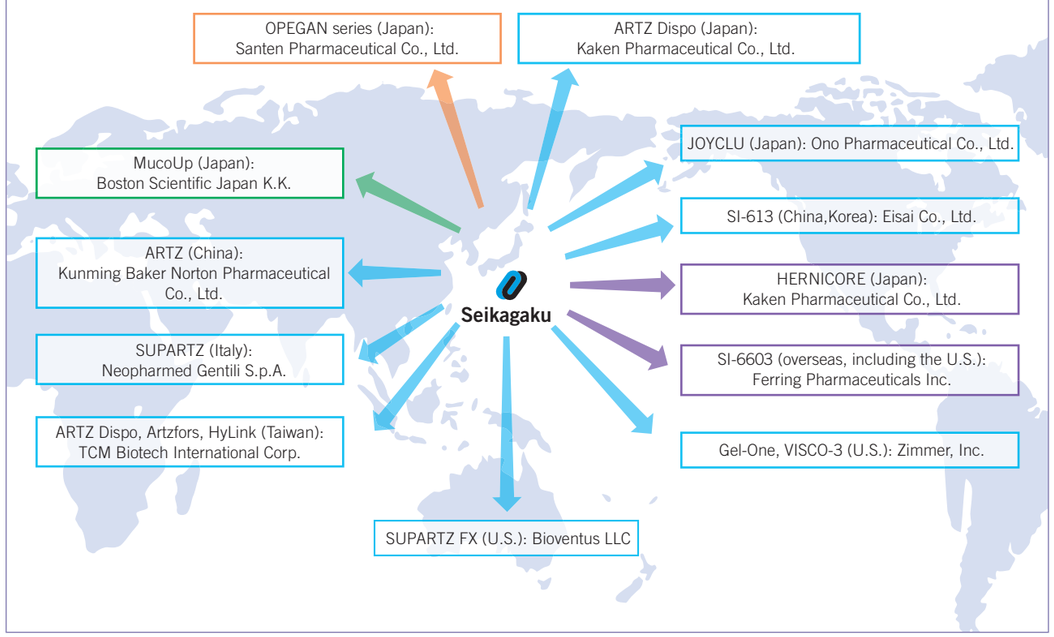
[Supply Chain for Main Products]



[Key Alliances with Companies in Japan and Overseas (Including Products under Development)]

Joint function improving agent/ Treatment of osteoarthritis | Ophthalmic viscoelastic device | Treatment for lumbar disc herniation | Surgical aid for endoscopic mucosal resection

(As of September 30, 2024)



LAL business

Seikagaku is engaged in the development of the LAL business in Japan, which is mainly used in quality control of injectable pharmaceuticals and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.

Wholly owned subsidiary Associates of Cape Cod, Inc. (ACC) handles overseas business development. ACC is the first company in the world to successfully develop endotoxin-detecting reagents from limulus amebocyte lysate (LAL), and it obtained U.S. Food and Drug Administration approval in 1977. ACC plays an important role in the overseas business expansion through its global sales network, mainly in the U.S. and Europe, through the manufacturing and sales of endotoxin-detecting reagents, as well as beta-glucan-detecting in vitro reagent to diagnose invasive fungal disease.

Furthermore, Seikagaku has successfully developed the world's first product consisting of recombinant proteins of Factor C, Factor B, and a coagulating enzyme precursor, which are components of horseshoe crab blood cells. Seikagaku currently sells the gene-recombinant endotoxin-detecting reagent PyroSmart NextGen in Japan, North America, and Europe.

Production

Seikagaku steadily manufactures high-quality products at its two pharmaceutical manufacturing plants in Japan and endotoxin-detecting reagent manufacturing plant in the U.S. and plant related to CDMO business in Canada.



Production structure compliant with global standards

Companies that manufacture pharmaceuticals and medical devices must comply with the current regional regulations and engage in stable, continuous manufacturing. In order to deliver high-quality products to patients, Seikagaku complies with Good Manufacturing Practice in Japan, the U.S., and Europe and strives for ever more rigorous manufacturing processes.
Also, in the area of manufacturing control and quality control, we use computer systems to improve the completeness of records and work to improve production efficiency through rigorous regular checks, elimination of human error, and improvement of manufacturing processes. We will continue to pursue continuous improvement so as to manufacture and supply high-quality products that comply with global standards.

Ensuring a stable supply of products

It is important for pharmaceutical companies to provide stable supplies. Seikagaku prepares for major disasters and other risks by diversifying raw materials and maintaining appropriate inventory levels. At the Takahagi Plant, responsible for manufacturing the finished products, we have introduced a quake-absorbing structure that helps isolate the main production buildings from earthquakes. Through these measures, we now have a system capable of stable, reliable product production even in an emergency.

Furthermore, to cope with product supply risk from disruption of distribution in a disaster, we maintain a certain level of product inventory and have pharmaceutical warehouses in two separate locations: at the Takahagi Plant in Ibaraki Prefecture near Tokyo and in Hirakata City, near Osaka.

[Overview of Domestic Production Sites]

Takahagi Plant (Takahagi City, Ibaraki Prefecture)

The Takahagi Plant is responsible for manufacturing finished pharmaceuticals and medical devices, including the joint function improvement agents that are Seikagaku's mainstay products. Today, the Takahagi Plant occupies a site of approximately 86,000 square meters and has five production buildings and some 330 employees. (As of the end of March 2024).

The Takahagi Plant is one of the world's largest manufacturing sites for hyaluronic acid pre-filled syringe formulations*. Sterility assurance is strictly required for the manufacture of injectable formulations, and the plant has minimized the risk of contamination by implementing unattended, automated manufacturing processes. The plant possesses facilities and equipment that can be adapted to optimal sterilization methods suited to the product characteristics.

*A kit with an injectable syringe that has been filled with solution.



Kurihama Plant (Yokosuka City, Kanagawa Prefecture)

The Kurihama Plant, which manufactures bulk products and has a long history since its establishment in 1947, has approximately 120 employees as of the end of March 2024 and manufactures high-purity hyaluronic acid and chondroitin sulfate, primarily for use as active pharmaceutical ingredients.

The most important characteristic of the Kurihama Plant is that it specializes in the manufacturing of bulk products by extraction and fermentation. The plant applies advanced chondroitin sulfate extraction and fermentation technologies nurtured over many years since the founding of Seikagaku and has expertise in the efficient manufacture of high-purity bulk products from chicken combs, the raw material of hyaluronic acid, and shark cartilage, the raw material of chondroitin sulfate.

The Kurihama Plant is also responsible for the manufacturing processes for condoliase, the active pharmaceutical ingredient of HERNICORE, a treatment for lumbar disc herniation.

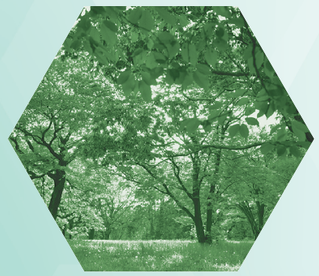


Information on the overseas manufacturing sites, U.S.-based Associates of Cape Cod, Inc., and Canada-based Dalton Chemical Laboratories, Inc., is provided in the section "Overseas Subsidiaries" on page 58.

Sustainability Progress

Sustainability Management ····· P33
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Sustainability Management

Basic Policy on Sustainability

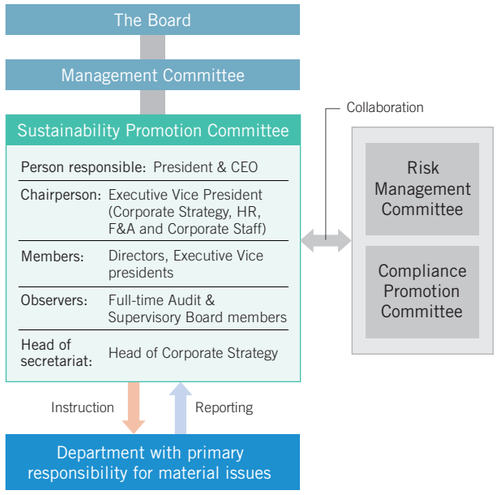
Seikagaku Corporation Group, guided by the core values expressed in the motto Creativity, Fairness, Dreams and Passion, aims to sustainably develop together with society by living up to its management creed: “Under the principle of respect for learning, we contribute to human well-being by creating and supplying the world with safe and useful pharmaceutical products based on glycoscience.”

In undertaking this, we meet the expectations of our diverse stakeholders and practice behaviors aimed at creating fair and honest relationships on the basis of high corporate ethical standards that reflect profound awareness of our social mission and responsibilities as a life sciences company.

On the basis of these ideals, Seikagaku Corporation Group seeks to grow as a corporate group that is valued by the world by providing a stable supply of truly useful, high-quality products created from innovative R&D activities and will contribute to the health and well-being of people around the world by working toward the sustainable development of the Earth and society.

Sustainability promotion structure

Seikagaku has designated the president & CEO as the person responsible for promotion of sustainability-related activities and established the Sustainability Promotion Committee, which is chaired by the executive vice president. The committee discusses the policy on sustainability-related activities, promotion measures, and other sustainability-related matters and verifies and assesses progress toward objectives. Important matters are reported on and considered at meetings of the Board following deliberation by the Management Committee.



1) Board of Directors

The Board decides, gives instructions, and supervises important matters relating to basic management policies, the mid-term management plan, the business plan, etc.

2) Management Committee

The Committee discusses and decides important matters relating to corporate management, such as the conclusion of important contracts, establishment of company rules and regulations, and formulation and modification of business execution plans.

3) Sustainability Promotion Committee

The Committee formulates basic policies and promotion measures relating to sustainability promotion, examines and assesses progress, and provides guidance and education. As a rule, the Committee meets twice yearly, and agenda items and deliberation results are reported or submitted for consideration by the Board of Directors and Management Committee as the chairperson considers necessary.

Fiscal 2023 Results

- **Establishment of ESG-related key performance indicators and numerical targets**
  https://www.seikagaku.co.jp/en/sustainability/materiality.html
- **Disclosure of ESG-related data**
  https://www.seikagaku.co.jp/en/sustainability/esgdata.html
- **Analysis of climate change-related risks and opportunities**
  https://www.seikagaku.co.jp/en/sustainability/tcfd.html
  P35
- **Implementation of measures to achieve the CO_2 emissions reduction target for 2030 (energy decarbonization, updating of facilities)**
  P34
- **Provision of sustainability training to executives and managers (on information disclosure at Seikagaku in view of trends in human capital and legal disclosure, etc.)**
- **Holding of employee-participatory workshops on human capital and career development**
- **Conduct of an employee engagement survey**
- **Awarded a Silver sustainability rating for 2023 by EcoVadis***
  https://www.seikagaku.co.jp/en/sustainability/external_evaluation.html

Future Initiatives

- **Implementation of CO_2 emissions reduction measures (facilities replacement and updating, procurement of renewable energy, etc.)**
- **Establishment of a supply chain risk assessment process**
- **Enhancement of communication with business partners**
- **Cultivation and development of human resources capable of creating new value**
- **Creation of an environment and development of systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities**

* EcoVadis is a company that operates a platform for assessing the sustainability supply chains of more than 130,000 businesses in 180 countries worldwide using original assessment criteria related to four sustainability themes: Environment, Labor & Human Rights, Ethics, and Sustainable Procurement (as of 2023).

Materiality 6

E
Environment

Basic Policy on Sustainability

Seikagaku Corporation recognizes that the global warming problem is a critical challenge facing the world and considers contributing to the realization of a sustainable society an important mission for companies. As a pharmaceutical company and as a member of society, Seikagaku Corporation aims to achieve balance between environmental measures and the Company’s growth and will implement initiatives to achieve business activities with low impact on the environment.

[Environmental Policy]
https://www.seikagaku.co.jp/en/sustainability/policy.html

Initiatives for environmental impact reduction and CO_2 emissions reduction

Keenly aware of the importance of protecting the global environment and responsibilities associated with manufacturing activities, Seikagaku observes environment-related laws and regulations and voluntarily engages in environmentally friendly business activities. We aim to balance environmental measures and business growth by continuing the energy-saving activities implemented heretofore and strengthening initiatives for efficient utilization of water resources, waste reduction and recycling, and other environmental improvements.

In response to the revised Act on Rationalizing Energy Use, which came into effect in April 2023, we reorganized the previous Energy Conservation Promotion Committee into the Energy Management Committee for the purpose of adding CO_2 emissions reduction and energy demand optimization as activities objectives along with the previous energy conservation activities. The Committee manages energy use and conducts education and training related to improvement measures and energy management for the purpose of achieving energy use reduction targets established at each business site. Furthermore, we have put in place a structure for increasing company-wide energy efficiency in which the Committee compiles information on actual energy use and CO_2 emissions volume and reduction measures each fiscal year and reports and discusses the data with the Management Committee. At the Takahagi Plant, the production site that uses the most energy, we have increased thermal efficiency and reduced CO_2 emissions by updating boilers to convert boiler fuel from heavy fuel oil A to high-efficiency liquid natural gas (LNG). Furthermore, we have reduced energy use through initiatives such as converting to LED lighting fixtures, updating air conditioning chillers, and reusing waste heat at production sites and laboratories.

In this way, by continuously engaging in energy conservation activities company-wide, we have achieved energy efficiency improvement exceeding the increase in energy use resulting from increased production and achieved our average energy reduction rate targets for the five years up to fiscal 2023. Also, to ascertain CO_2 emissions throughout the supply chain, we have estimated Scope 3 emissions and disclosed the estimates on the corporate website. Going forward, we intend to refine the estimates and gradually pursue emissions reduction, prioritizing important categories. To reduce environmental impacts throughout the supply chain, we also want to undertake switching to different product materials and recycling of waste materials.

TOPICS

From energy conservation to energy management

Seikagaku considers addressing climate change an important management priority and is implementing measures to combat climate change. Since June 2022, Seikagaku has disclosed the status of its response to the TCFD recommendations and to climate-related risks and opportunities. We plan to reduce CO_2 emissions by 46% by 2030 compared to fiscal 2017 by implementing four main initiatives: energy conservation, fuel conversion, updating of equipment, and introduction of renewable energy.

To do its part to achieve this target, the Takahagi Plant launched the 2030 Promotion Committee and is formulating and implementing plans. Currently, the plant is implementing a plan to install solar carports equipped with photovoltaic power generation facilities at its parking lot for the purpose of utilizing renewable energy to supply some of the power used to maintain air conditioning in the clean rooms used for production. In addition, we are implementing various initiatives to optimize energy use company-wide, such as demand response* at the laboratories and procurement of CO_2-free electricity at our four business sites in Japan.



Artist’s rendering of solar carports equipped with photovoltaic power generation facilities at the Takahagi Plant

* Demand response refers to changing electricity demand patterns by encouraging users to intelligently control their power consumption.

Materiality 6

E
Environment

Information Disclosure Based on the TCFD Recommendations

Seikagaku Corporation considers addressing climate change to be an important management priority and is implementing measures to combat climate change. Since June 2022, Seikagaku has disclosed the status of its response to the TCFD recommendations and to climate-related risks and opportunities.

Governance

In accordance with the Basic Policy on Sustainability, Seikagaku Corporation has identified by a resolution of the Board of Directors important issues that should be addressed on a priority basis (materiality) in the interest of achieving sustainable growth for Seikagaku and realizing a sustainable society.

We established the Sustainability Promotion Committee for the main purpose of addressing sustainability-related issues. In principle, the Committee meets twice a fiscal year to discuss the action policy for climate change issues, promotion measures, and related matters and to examine and assess progress. Also, climate change risks and opportunities are included among the group-wide risks evaluated by the Risk Management Committee, discussed by the Sustainability Promotion Committee, and reported to the Board of Directors, and the Board monitors and oversees progress in addressing these risks. The president & CEO serves as the officer responsible for the Sustainability Promotion Committee and Risk Management Committee.

Strategy

To conduct a climate-related risk and opportunity materiality assessment, we used the following scheme to identify and assess scenarios for three categories: transition risks, physical risks, and opportunities. In addition to the Net Zero Emissions by 2050 Scenario* (NZE) proposed by the Intergovernmental Panel on Climate Change and the International Energy Agency (IEA), which assumes a temperature rise of 1.5ºC, and the IEA's Stated Policies Scenario (STEPS), which assumes a 4ºC rise, we carefully examined internal and external information and assessed the potential effects of climate-related risks and opportunities on businesses, strategy, and financial planning.

* Seikagaku analyzes risks and opportunities based on the following scenarios:
Net Zero Emissions by 2050 Scenario (NZE): 1.5°C rise
(STEPS): 4°C rise

Scenario Analysis Scheme

Step 1	Step 2	Step 3	Step 4
Collection and analysis of basic information on climate change	Climate change scenario hypothesis setting	Risk and opportunity analysis for each scenario	Qualitative assessment of financial impacts

Risk management

In risk management, each division and department implements initiatives in response to risks and opportunities in accordance with the Corporate Risk Management Regulations. The Sustainability Promotion Committee, established in December 2021, and the Risk Management Committee share information on climate change risks, integrate and manage these risks as a form of business risk, and periodically report important risks to the Board of Directors.

Risk and opportunity analysis based on medium- and long-term scenarios

Transition risk

Risks and Opportunities	Details	Scale of Financial Impacts 1.5℃ / 4℃	Time Frame	Response and Resilience
Policy and legal risk	Rising costs due to tightening of regulations, such as introduction of a carbon tax	Medium / Medium	Medium to long term	Mitigation of carbon tax burden through promotion of energy conservation and introduction and expanded use of renewable energy; cost reductions from initiatives such as reduction of raw materials use
Market risk	Rising costs due to introduction of eco-friendly raw materials, etc.	Medium / Medium	Medium to long term	Mitigation of carbon tax burden through promotion of energy conservation and introduction and expanded use of renewable energy; cost reductions from initiatives such as reduction of raw materials use
Reputation risk	Investor resistance or decline in personnel recruitment opportunities due to inadequate sustainability information disclosure, etc.	Medium / Small	Short to medium term	Pursuit of corporate value enhancement and greater opportunities to secure investment and personnel through proactive sustainability information disclosure

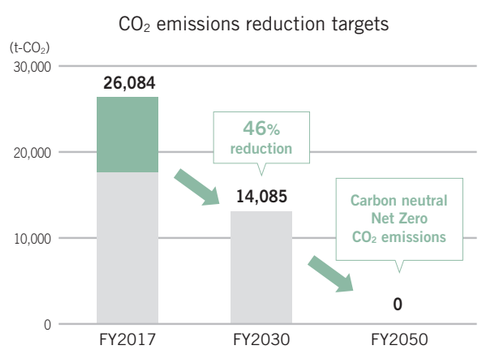
Physical risk

Risks and Opportunities	Details	Scale of Financial Impacts 1.5℃ / 4℃	Time Frame	Response and Resilience
Acute	Risk of damage to production facilities, etc., resulting from increasingly serious extreme weather events; rising costs of restoration and prevention measures; temporary shutdowns due to supply chain disruption	Medium / Large	Medium to long term	Damage minimization through a continuous review of the business continuity plan (BCP), upgrading of BCP measures and strengthening of impact assessment and response capabilities along supply chains
Chronic	Declining outpatient numbers due to a healthcare crunch accompanying climate change-related spread of infectious disease	Medium / Medium	Long term	Promotion of R&D of long-acting drugs that entail little outpatient burden
Chronic	Decrease in natural resources used as raw materials or quality deterioration due to the impact of climate change on ecosystems	Small / Medium	Medium to long term	Promotion of research on substitute raw materials and transition from biological raw materials to recombinant raw materials, such as fermented materials

Opportunities

Risks and Opportunities	Details	Scale of Financial Impacts 1.5℃ / 4℃	Time Frame	Response and Resilience
Energy and resource efficiency	Production facilities efficiency improvement	Small / Small	Medium to long term	Cost reductions from promotion of energy conservation and introduction and expanded use of renewable energy
Products, services, and markets	Climate-change related spread of infectious disease	Medium / Medium	Long term	Promotion of R&D in the infectious disease diagnosis field, etc.

Metrics and targets



CO_2 emissions reduction targets (Scope 1 & 2: non-consolidated)

- 46% reduction by 2030 (compared to fiscal 2017)
- Pursuit of carbon neutrality by 2050
- Scope 3 calculation (disclose by 2025)

Effective measures to consider in the medium to long term

- Thorough energy conservation actions and educational activities
- Installation of high-efficiency equipment and solar power generation facilities
- Procurement of carbon-free energy and credits

Materiality 6

E
Environment

Initiatives for Biodiversity

Recognizing the importance of biodiversity in business as a life sciences company, Seikagaku Corporation strives for biodiversity preservation and the sustainable use of biological resources.

[Biodiversity Policy]
https://www.seikagaku.co.jp/en/sustainability/biodiversity.html

Horseshoe crab conservation activities and development of a recombinant reagent at Associates of Cape Cod, Inc.

Since Seikagaku's U.S. subsidiary Associates of Cape Cod, Inc. (ACC) manufactures and sells reagents using a substance extracted from horseshoe crab blood cells as a raw material, it continuously engages in horseshoe crab conservation activities to protect this precious natural resource. The total number of American horseshoe crabs that ACC has released in the Commonwealth of Massachusetts had reached about 1.35 million as of March 31, 2024.

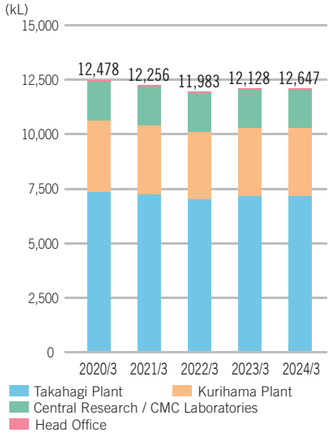
Also, in 2019 ACC began providing assistance for activities to maintain the population of Asian horseshoe crabs, which are said to be at risk of extinction. Maintaining the population involves growing survivable juveniles produced by in vitro fertilization of sperm and eggs and releasing them into the natural environment. ACC has long engaged in this activity and accumulated related technology and expertise. This assistance will be made available to academic institutions and private sector researchers around the world. Organizations receiving assistance are granted a license to use intellectual property relating to horseshoe crabs owned by ACC free of charge and are also provided with instructions regarding in vitro fertilization methods and training in the operation of highly efficient aquaculture equipment.

In parallel with these conservation activities, ACC has also focused on development of gene-recombinant endotoxin-detecting reagents that can be manufactured without using blood harvested from horseshoe crabs. PyroSmart NextGen, launched by ACC for sale in overseas markets in April 2021 and launched by Seikagaku for sale in Japan in May, was commercialized by ACC based on the results of R&D conducted for many years at Seikagaku. Since PyroSmart NextGen follows the same cascade pathway as naturally sourced products, the same test methods and instrumentation can be used when the product is substituted for traditional naturally sourced reagents. ACC seeks to contribute to sustained environmental conservation by providing the option of choosing a gene-recombinant reagent in addition to taking measures to maintain the population of horseshoe crabs.

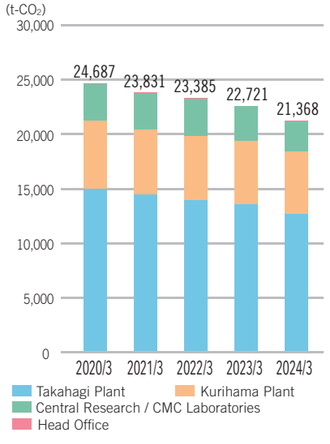
The Seikagaku Group will continue to actively support activities to conserve horseshoe crab populations and strive to use this resource in a sustainable manner.

Environmental Highlights

Energy Use



CO_2 Emissions





Horseshoe crab juveniles



Released juveniles

Materiality 5

S
Social

Social Contribution Activities

Seikagaku engages in initiatives to address social and environmental problems in pursuit of harmony and continuous growth together with local communities. And we pursue respect for learning by engaging in global research assistance and sponsoring activities that support the development of glycoscience.

Glycoforum, a website for comprehensive information on glycoscience research

https://www.glycoforum.gr.jp/index.html

Since 1997, Seikagaku has operated Glycoforum, an academic website specialized in glycoscience research that shares information about research findings to contribute to the development of glycoscience, which is one of Seikagaku's areas of specialization.

As a portal site for glycoscience information, the website disseminates in a timely manner scientific papers from researchers active on the cutting-edge of the field, explanations of technical terms, and academic conference information. The site enjoys strong support from researchers in Japan and overseas.



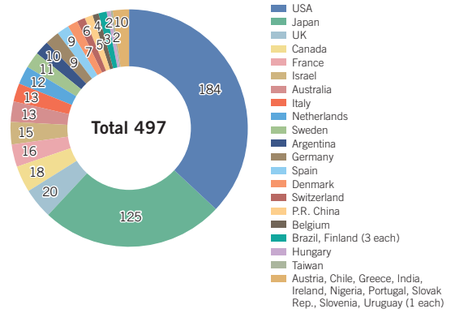
Support for the Mizutani Foundation for glycoscience

https://www.mizutanifdn.or.jp/index.html

The Mizutani Foundation for Glycoscience, a public interest incorporated foundation, was established in 1992 with an endowment from the late Masakane Mizutani, former president of Seikagaku Corporation, for the purpose of contributing to the welfare of humanity through the advancement and development of glycoscience. The foundation provides research grants to glycoscience researchers in Japan and overseas and supports conferences. In fiscal 2023, the foundation provided research grants totaling ¥71.12 million to 14 grant recipients.

Seikagaku endorses the purpose of the Foundation and has continuously supported its activities since its founding.

Number of Grant Recipients by the Mizutani Foundation for Glycoscience (By country and area: 1993–2024)



TOPICS

Encouraging patients to seek early diagnosis and treatment

- **Knee osteoarthritis *Hiza Ikiiki* (Sprightly Knees), a website for provision of information concerning knee osteoarthritis to the general public**
  Knee osteoarthritis is a disorder by which the knee joint is strained due to aging, excessive exercise, or weight increase and the cartilage gradually wears away. *Hiza Ikiiki* explains basic knowledge concerning knee osteoarthritis and diagnosis and treatment methods in an easy to understand way.

https://www.ehiza.jp (Japanese only)



- **Koshi-hernia.jp, a website for the provision of information concerning lumbar disc herniation to the general public**
  Koshi-hernia.jp explains basic knowledge concerning lumbar disc herniation and its symptoms in an easy to understand way. It also provides information on changes in symptoms according to the season or weather, the impact of the disorder on work and lifestyles, and other information obtained from the findings of online patient surveys.

https://koshi-hernia.jp/ (Japanese only)



Through these websites, Seikagaku will provide correct knowledge and information to enable as many patients as possible to obtain early, correct treatment.

Materiality 5

S
Social

Promotion of Diversity and Development of Human Resources

Seikagaku Corporation recognizes that respecting human rights through business activities is important for remaining a company that contributes to healthy and fulfilling lives for people around the world, and also creates a prosperous future. Upholding and respecting human rights in accordance with the UN Guiding Principles on Business and Human Rights, we hereby initiate the Seikagaku Corporation Human Rights Policy (the "Policy").

Also, to proceed with active hiring and promotion of female employees and ensure that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth, we are engaging in organizational operation and staff assignments that enable individuals to demonstrate their full potential.

[Human Rights Policy]
https://www.seikagaku.co.jp/en/sustainability/our_policy/humanright.html

Development of human resources

Seikagaku Corporation considers human resources to be an important corporate asset and works to cultivate human resources capable of creating new value. To ensure that the contributions and successes of diverse employees are the driver of Seikagaku's sustained growth, we will proceed with creation of an environment and preparation of systems, programs, and mechanisms to enable all employees to fully demonstrate their capabilities. Seikagaku also strives to provide fields for each person to grow and thrive in. We endeavor to cultivate autonomous employees who go about their work with enthusiasm and pride and produce results. We promote upskilling and career development through a combination of systematic education in various training programs, workplace education through day-to-day work, and job rotation.

The curriculum for systematic education is depicted in the diagram below. We conduct a variety of training programs for everyone from young employees to executives with the objective of promoting the growth of individual employees and the Company.

Work-life balance

To help its employees achieve a good work-life balance, Seikagaku has introduced flextime at all business sites, including laboratories and plants, and established a weekly "no overtime day."

To help employees balance their personal lives with their work, Seikagaku encourages them to develop their own work styles. For example, we now have a reduced-working-hours system for employees who provide childcare and nursing care, and employees may also accumulate lapsed annual paid leave for use during prolonged illnesses or to cope with extended childcare and nursing care needs.

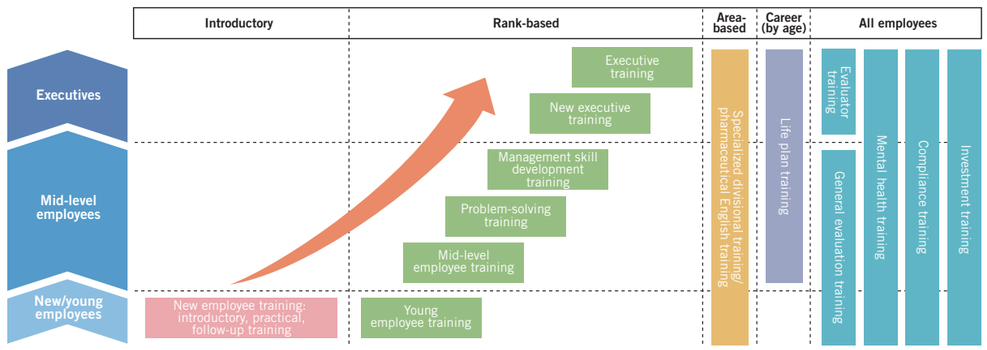
Since 2021, we have operated a work-from-home system to enable employees to select from among diverse work styles. This also makes it possible to increase productivity though greater operational efficiency and maintain continuity of operations in the event of a disaster.

We have begun operating a work interval system at both plants in the interest of employee health and safety.

In fiscal 2023, the average paid leave utilization rate for Seikagaku employees was 83.7%, the return rate from childcare leave was 93.8%, and the childcare leave utilization rate by men was 55.6%. Furthermore, Seikagaku creates employee friendly workplaces through staff assignments that correspond to the nature and amount of work, improvement of workplace environments, and correction of long working hours.

The Human Resources Seikagaku Seeks
https://www.seikagaku.co.jp/en/sustainability/resource.html

Training Systems



Enhancement of employee engagement

Seikagaku has decided to conduct an employee engagement survey beginning in fiscal 2023 as an aspect of human capital initiatives. The survey results for company-wide overall satisfaction for fiscal 2023 were a rating of B and a score of 3.41 points (on a 5-point scale). We will continue to periodically conduct the survey and utilize the results in considering and implementing measures to enhance employee engagement.

Diversity management

Seikagaku is creating an environment and developing systems, programs, and mechanisms to enable employees to fully demonstrate their capabilities and is implementing measures to support the advancement as part of diversity management efforts.

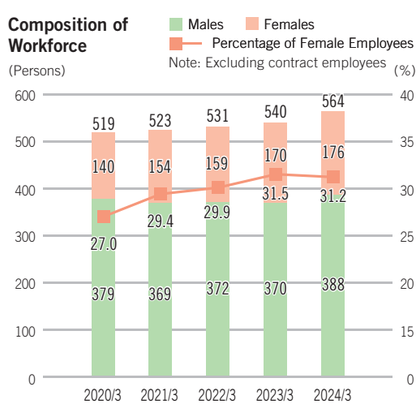
We are implementing measures for "Promotion of diversity and development of human resources," one of Seikagaku's material issues, and continuing efforts to create an organization in which all employees can fully demonstrate their capabilities.

In October 2022, we revised the previous single-track personnel promotion system to a multiple-track system to make possible personnel assignment and development that take aptitude into account.

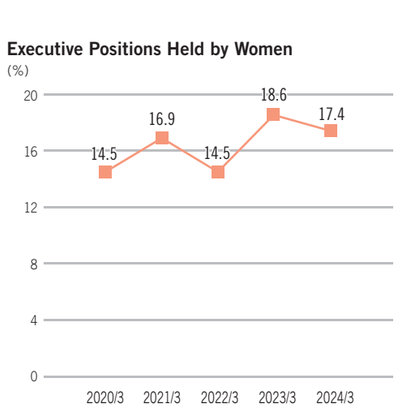
Mental healthcare

Since 2009, Seikagaku has implemented measures aimed at maintaining the physical and mental health of employees to vitalize workplaces and increase productivity. Specifically, we are improving the overall workplace environment by obtaining the advice and assistance of industrial physicians and public health nurses periodically and as needed, by conducting mental health care seminars for managers that utilize the results of annual stress checks, and other means. We have also instituted an external hotline and counseling service that employees and family members can freely utilize and are developing a self-care support system to enable employees themselves to recognize physical disorders and stress and learn how to cope with them.

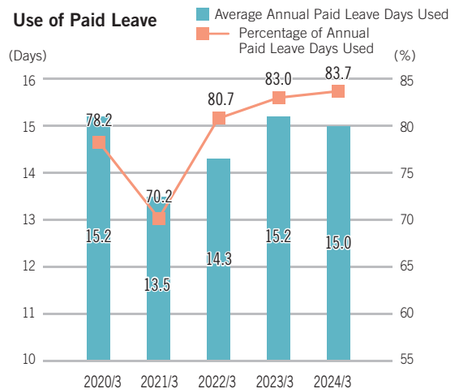
Composition of Workforce



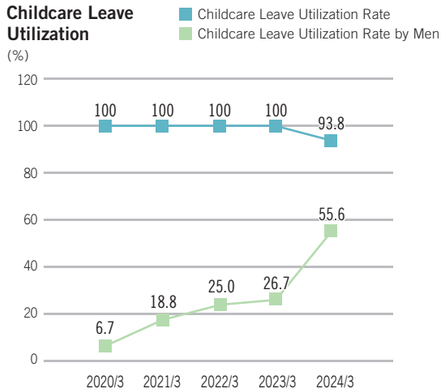
Executive Positions Held by Women



Use of Paid Leave



Childcare Leave Utilization



*The figures provided on this page are all on a non-consolidated basis.

G
Governance

Corporate Governance

Members of the Board (as of June 21, 2024)

Directors



President & CEO
Ken Mizutani

Term of office as Director: 34 years
Number of the Company's shares owned: 471,193 shares

Apr. 1970	Joined Mitsubishi Chemical Industries Limited (current Mitsubishi Chemical Corporation)
Aug. 1988	Joined the Company
June 1990	Member of the Board, Head of Research Biologicals and Diagnostics Marketing
June 1993	Member of the Board, Senior Executive Vice President responsible for Planning and Manufacturing
June 1998	Member of the Board, Senior Executive Vice President responsible for Marketing
June 2000	Member of the Board, Senior Executive Vice President and Head of Central Research Laboratory
June 2002	Representative Director and Member of the Board, Senior Executive Vice President responsible for Pharmaceuticals, Fine Chemicals, Oral Care, Glycoforum, and Head of Central Research Laboratory
June 2005	Representative Director and Member of the Board, President & Chief Executive Officer (CEO)
June 2018	Representative Director and Member of the Board, President & CEO and Head of Manufacturing
June 2019	Representative Director and Member of the Board, President & CEO (current position)



Executive Vice President
Reliability Assurance
Toshiyuki Okada

Term of office as Director: 7 years
Number of the Company's shares owned: 20,118 shares

Apr. 1989	Joined Dow Corning Japan Co., Ltd.
Sept. 1996	Joined Johnson & Johnson Medical K. K. (current Johnson & Johnson K. K.)
Feb. 2015	Vice President and Chief Technology Officer
Sept. 2015	Joined the Company Executive Vice President, Deputy responsible for Quality Assurance, Pharmacovigilance and Regulatory Affairs Auditing
June 2016	Executive Vice President responsible for Quality Assurance, Pharmacovigilance and Regulatory Affairs Auditing
Jan. 2017	Executive Vice President responsible for Marketing
June 2017	Member of the Board, Executive Vice President responsible for Marketing
June 2018	Member of the Board, Executive Vice President responsible for Business Development & Marketing
June 2023	Member of the Board, Executive Vice President responsible for Reliability Assurance (current position)



Executive Vice President
Research & Development
Yosuke Funakoshi

Term of office as Director: 6 years
Number of the Company's shares owned: 20,718 shares

Apr. 1990	Joined ONO PHARMACEUTICAL CO., LTD.
June. 2008	Joined Takeda Pharmaceutical Company Limited
Aug. 2012	Takeda Global Research & Development Center Inc. (current Takeda Development Center Americas, Inc.) Vice President of Strategic Project Management
Aug. 2014	Joined the Company Senior Vice President and assistant to Senior Executive Vice President responsible for Research & Development
Oct. 2014	Senior Vice President and Head of Clinical Development
June 2016	Executive Vice President, Deputy responsible for Research & Development and Head of Clinical Development
June 2017	Executive Vice President responsible for Research & Development and Head of Clinical Development
June 2018	Member of the Board, Executive Vice President responsible for Research & Development and Head of Clinical Development
Oct. 2021	Member of the Board, Executive Vice President responsible for Research & Development (current position)



Outside Member of the Board
Mio Minaki

Term of office as Director: 5 years
Number of the Company's shares owned: —

Apr. 1999	Joined MIT Corporation
Oct. 2003	Public prosecutor, Tokyo District Public Prosecutors Office
Apr. 2004	Public prosecutor, Osaka District Public Prosecutors Office
Apr. 2005	Public prosecutor, Fukuoka District Public Prosecutors Office
Apr. 2014	Litigation Department Attorney, Ministry of Justice Fukuoka Legal Affairs Bureau
Apr. 2016	Public prosecutor, Tokyo District Public Prosecutors Office
Apr. 2017	Assigned as Head of Legal Affairs Department to Agriculture, forestry and fisheries Fund corporation for Innovation, Value-chain and Expansion Japan
Apr. 2019	Admitted to the bar in Japan
Apr. 2019	Joined Minaki & Kitazawa Law Office (current position)
June 2019	Outside Director of the Company (current position)



Outside Member of the Board
Yasuyuki Sugiura

Term of office as Director: 3 years
Number of the Company's shares owned: —

Apr. 1978	Joined Mitsubishi Corporation
Apr. 1998	General Manager, Washington Office, Mitsubishi International Corporation
Apr. 2006	CFO and SVP in charge of Corporate Department, Mitsubishi International Corporation
Apr. 2009	Executive Officer and General Manager, Corporate Communications Department, Corporate Strategy & Planning Division
Apr. 2012	President & Director and Head of Chicago Branch, Mitsubishi International Corporation
Apr. 2013	Executive Vice President, Mitsubishi Corporation and President & Director, Mitsubishi Corporation (Americas)
Apr. 2016	Advisor, Mitsubishi Corporation (current position)
June 2017	Managing Director, Toyo Bunko (current position)
June 2021	Outside Director of the Company (current position)

Audit & Supervisory Board Members



Audit & Supervisory Board Member
Mikako Torii

Term of office as Audit & Supervisory Board Member: 2 years
Number of the Company's shares owned: 14,059 shares

Apr. 1988	Joined the Company
June 2011	Head of Corporate Staff
June 2015	Executive Vice President and Head of Corporate Staff
June 2022	Audit & Supervisory Board Member (current position)



Outside Audit & Supervisory Board Member
Hideki Hayashi

Term of office as Audit & Supervisory Board Member: —
Number of the Company's shares owned: —

Apr. 1987	Joined The Mitsubishi Bank, Limited (current MUFG Bank, Ltd.)
May 2010	Deputy General Manager, Retail Administration Department
Jan. 2013	Representative Director and President, MU Center Service Tokyo Co., Ltd
June 2018	Representative Director and President, MU Business Engineering, Ltd. (current Mitsubishi UFJ Information Technology, Ltd.)
June 2021	Standing Audit & Supervisory Board Member, NIPPON RECORD KEEPING NETWORK Co., Ltd.
June 2024	Outside Audit & Supervisory Board Member of the Company (current position)



Outside Audit & Supervisory Board Member
Shinkichi Matsuo

Term of office as Audit & Supervisory Board Member: 5 years
Number of the Company's shares owned: —

Apr. 1991	Joined Mitsubishi Electric Corporation
Apr. 1993	Joined Yokohama City Government
Oct. 1995	Joined Ota Showa Audit Corporation (current Ernst & Young ShinNihon LLC)
Apr. 1999	Registered as a certified public accountant
June 2018	Representative Director, NextLeap Co., Ltd. (current position)
June 2019	Outside Audit & Supervisory Board Member of the Company (current position)



Outside Audit & Supervisory Board Member
Takayuki Maruyama

Term of office as Audit & Supervisory Board Member: 4 years
Number of the Company's shares owned: —

Apr. 2000	Admitted to the bar in Japan
Apr. 2000	Joined Nagashima Ohno & Tsunematsu
Sep. 2005	Joined Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP
Jan. 2006	Admitted to the bar in New York State, US
Feb. 2008	Joined OH-EBASHI LPC & PARTNERS (current position)
June 2020	Outside Audit & Supervisory Board Member of the Company (current position)



Outside Audit & Supervisory Board Member
Wakako Mitani

Term of office as Audit & Supervisory Board Member: 1 year
Number of the Company's shares owned: —

Apr. 2000	Admitted to the bar in Japan
July 2001	Joined Tanabe & Partners (current position)
June 2023	Outside Audit & Supervisory Board Member of the Company (current position)

Executive Vice Presidents

Overseas subsidiaries, Marketing Activity Supervision, Glycoscience Networking and Medical Affairs Executive Vice President
Yuji Shimojima

HR, F&A and Corporate Staff
Executive Vice President
Kazushi Takeda

Head of Production
Executive Vice President
Masayuki Ito

Business Development & Marketing
Executive Vice President
Ryoji Tomokiyo

Notes:
1. Ken Mizutani, Toshiyuki Okada, and Yosuke Funakoshi concurrently serve as Executive Vice President.
2. Terms of office are as of June 21, 2024.
3. Number of the Company's shares owned is as of March 31, 2024.

Basic concept

In accordance with the management creed, “We create safe and useful products for human well-being with basic research based on glycoscience” and on the basis of profound awareness of our social mission and responsibilities as a pharmaceutical company, Seikagaku seeks to increase the speed of transparent and fair decision-making and strengthen oversight of business execution and is focusing on development of internal control systems, including for compliance and risk management. Our policy is to aim for sustainable growth and corporate value enhancement by striving to further strengthen corporate governance, which we view as an important management priority, and building a management system that rewards the trust of our shareholders and other stakeholders, and of society at large, through these initiatives.

Corporate governance structure

The Company has adopted a company with an Audit & Supervisory Board governance system, having determined that the most effective and appropriate form of corporate governance for the Company is for the Board of Directors to oversee business execution and for the Audit & Supervisory Board to perform auditing and oversight in cooperation with the accounting auditor and Audit Department. Furthermore, the Company has introduced an executive vice president system to separate management oversight by the Board of Directors from business execution and, in accordance with the basic policy determined by the Board of Directors, as a rule holds weekly Management Committee meetings to discuss important management matters.

The Board of Directors has established the Nomination and Remuneration Committee, comprising the president & CEO and all outside members of the Board, to advise on matters concerning selection of candidates for members of the Board and Audit & Supervisory Board members, remuneration for members of the Board, etc.

The Sustainability Promotion Committee discusses the policy on sustainability-related activities, promotion measures, and other matters and supervises their implementation, and the Compliance Committee discusses promotion measures to improve compliance effectiveness. The Risk Management Committee appropriately manages business risks and implements risk prevention measures.

Board of Directors

The Board of Directors comprises five members, including two outside members of the Board. The Company aims to enhance management oversight from an independent standpoint by appointing outside members of the Board to one-third or more of the Board seats.

To decide important matters stipulated in laws and regulations, the Articles of Incorporation, and rules for the Board, such as formulation of basic management policy, the mid-term management plan, and the annual management plan and the election of executive vice presidents, and to supervise business execution, in principle the Board holds regular monthly meetings and extraordinary meetings convened as necessary.

In fiscal 2022, the Board mainly deliberated matters related to management strategy, such as the mid-term management plan, important business strategies, and capital policy; matters related to sustainability, such as materiality; matters related to the settlement of accounts; matters related to corporate officers and remuneration; and matters related to subsidiaries.

To enable sufficient deliberation at Board meetings, as a rule, materials on matters for resolution and reporting matters are distributed to the Board members at least three days before meetings to provide time to review the materials.

Also, advance explanations of important agenda items are provided, as well as additional materials and supplemental explanations upon request.

A meeting of outside officers, comprising two outside members of the Board and four outside Audit & Supervisory Board members, undertakes improvement of Board operation by periodically analyzing and evaluating the effectiveness of the Board of Directors and reporting the results to the Board.

Both outside members of the Board are reported to the Tokyo Stock Exchange, Inc. as independent officers by the Company.

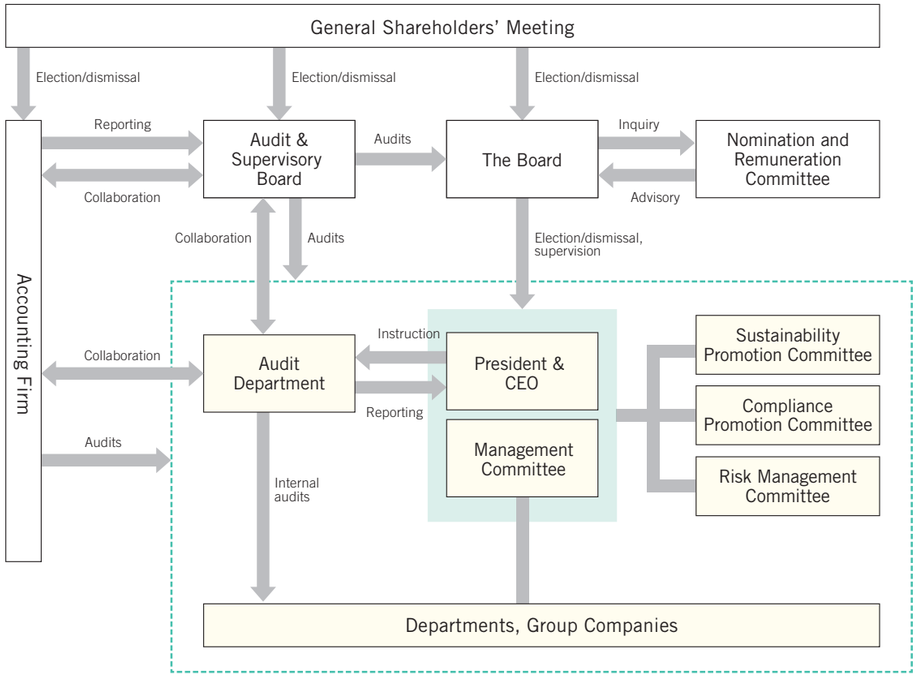
Enhancing functions of the Board of Directors

To achieve sustained growth and medium- and long-term enhancement of corporate value, following deliberation by the Nomination and Remuneration Committee, the Board of Directors determines skills required by the Board on the basis of basic management policy, the mid-term management plan, and other criteria. To maintain a structure capable of effectively fulfilling the Board’s role and duties, the Board selects candidates for corporate officer positions taking into consideration their knowledge, experience, abilities, and character, in addition to identified skills and Board diversity. Since the skills required by the Board of Directors constantly change according to the business environment and other factors, the Company periodically reviews them.

The term of office for members of the Board is one year with the aim of creating a management structure that would be able to adapt quickly and flexibly to changes in the business environment.

The outside members of the Board are responsible for oversight from an objective standpoint, a perspective that incorporates the common interests of shareholders, and is based on expert knowledge and insights into corporate management. The outside members of the Board also attend meetings held among the president & CEO, Audit & Supervisory Board members, and heads of each department to share views of the Company's business issues and the external environment.

Corporate governance structure



Main expertise and experience of directors and Audit & Supervisory Board members

Title	Name	Corporate management	Finance/ Accounting	Legal affairs/ Risk management	R&D	Global	Production/ Quality	Sustainability	Human Resources/ Diversity
President & CEO	Ken Mizutani	●		●	●		●	●	
Executive Vice President	Toshiyuki Okada	●			●	●	●	●	
Executive Vice President	Yosuke Funakoshi	●			●	●		●	
Outside Member of the Board	Mio Minaki			●					●
Outside Member of the Board	Yasuyuki Sugiura	●	●			●		●	●
Audit & Supervisory Board Member	Mikako Torii			●				●	●
Outside Audit & Supervisory Board Member	Hideki Hayashi	●	●	●					●
Outside Audit & Supervisory Board Member	Shinkichi Matsuo	●	●						
Outside Audit & Supervisory Board Member	Takayuki Maruyama			●		●			
Outside Audit & Supervisory Board Member	Wakako Mitani			●					●

Audit & Supervisory Board

The Audit & Supervisory Board, comprising five members, including one full-time Audit & Supervisory Board member, one full-time outside member, and three outside members, audits and supervises the execution of director's duties by each member of the Board.

Audit & Supervisory Board members attend meetings of the Board of Directors, offer advice and recommendations as necessary, interview directors in charge and corporate officers of subsidiaries in accordance with an annual plan, and exchange views with the president & CEO. Furthermore, they have periodic meetings with the accounting auditor and Audit Department and receive audit reports, audit results, and other reports, exchange views, and strive for cooperation.

The full-time members attend Management Committee meetings and other important meetings; examine minutes, approval documents, and other important documents; perform audits of business sites; and share information about business execution and development of the internal control system and confirmation of its status of operation with the outside members at Audit & Supervisory Board meetings.

The outside members perform the role of auditing and supervising the Board members' execution of duties from an objective standpoint, a perspective that incorporates the common interests of shareholders, based on expert knowledge and insights into corporate management. All four outside Audit & Supervisory Board members are reported to the Tokyo Stock Exchange, Inc. as independent officers by the Company.

Nomination and Remuneration Committee

To increase fairness, transparency, and objectivity relating to matters including the selection of candidates for members of the Board and Audit & Supervisory Board and determination of remuneration for members of the Board and enhance corporate governance, Seikagaku has established the Nomination and Remuneration Committee as a voluntary advisory body to the Board. The Committee comprises the president & CEO and both outside members of the Board, and the Company believes that appointing outside Board members as a majority of Committee members ensures independence.

The Committee deliberates and reports to the Board of Directors on its views on the composition of the Board, matters relating to the selection and dismissal of members of the Board and Audit & Supervisory Board members, and matters relating to remuneration for members of the Board. It also discusses and decides the amounts of basic compensation, performance-linked compensation, and earnings-linked compensation for members of the Board as well as matters for which decision-making has been delegated by the Board of Directors.

In fiscal 2023, the Committee deliberated matters relating to the selection of candidates for members of the Board and determination of remuneration for members of the Board, the amounts of monetary remuneration for individual members of the Board (including evaluation of each Board member pertaining to performance-linked compensation), and other matters.

Initiatives to strengthen corporate governance

(Fiscal year)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Number of members of the Board	9		7				8					5			6				5	
Number of outside members of the Board					1										2					
Number of female members of the Board															1					
Number of Audit & Supervisory Board members	4										5									
Number of outside Audit & Supervisory Board members	2										3									4
Number of female Audit & Supervisory Board members														1					2	
Advisory body to the Board of Directors																Nomination and Remuneration Committee				
Measures to improve Board of Directors effectiveness												Board of Directors' effectiveness evaluation								
												Outside Officers' meeting								
Term of office for members of the Board	2 years										1 year									
Executive vice president system									Executive vice president system											

Status of holding of Board of Directors and other meetings (fiscal 2023)

Organizational body	Composition	Frequency of convocation	Purpose
The Board*1	Members of the Board: 5 (including 2 outside members of the Board)	Once monthly in principle	The Board of Directors decides important matters stipulated in laws, the Articles of Incorporation and the Board of Directors Regulations, and oversees business execution. The Board of Directors met 14 times in fiscal 2023.
Audit & Supervisory Board	Audit & Supervisory Board members: 5 (including 4 outside members of the Board)	Once monthly in principle	The Audit & Supervisory Board discusses and decides important audit-related matters. The full-time members share information about business execution and development of the internal control system and its status of operation with the outside members at Audit & Supervisory Board meetings. The Audit & Supervisory Board met 14 times in fiscal 2023.
Nomination and Remuneration Committee	Members of the Board: 3 (including 2 outside members of the Board)	Meetings held as necessary	The Nomination and Remuneration Committee is a voluntary advisory body to the Board of Directors that reports to the Board on matters about which the Board has sought consultation, such as the nomination of candidates for corporate officer positions and remuneration for members of the Board and decides matters delegated by the Board. The majority of the committee members are independent outside members of the Board. The committee met three times in fiscal 2023.
Management Committee	Members of the Board: 3 Executive vice presidents: 4 Full-time Audit & Supervisory Board members: 2*2	Once weekly in principle	The Management Committee confers agendas of executive functions they have been tasked for implementation by the Board, based on the basic policy of the Board. The Management Committee met 45 times in fiscal 2023.

*1 Audit & Supervisory Board members also attend meetings of the Board of Directors. *2 Observers

Reasons for election and main expertise of outside members of the Board and outside Audit & Supervisory Board members

Category	Name	Reasons for election
Outside member of the Board	Mio Minaki	Ms. Mio Minaki has a wealth of experience developed over many years in the judicial field and insight relating to corporate legal affairs as a lawyer. The Company has judged that she is capable of appropriately fulfilling the role of outside member of the Board from a professional standpoint based on this knowledge and experience.
	Yasuyuki Sugiura	Mr. Yasuyuki Sugiura has been involved in corporate management for many years at a general trading company, mainly in the U.S. and Canada, and has a wealth of international experience and wide-ranging insight. The Company has judged that he is capable of appropriately fulfilling the role of outside member of the Board by reflecting this experience and insight in the Company's management.
Outside Audit & Supervisory Board member	Hideki Hayashi	Mr. Hideki Hayashi has a substantial degree of knowledge on finance and accounting from his experience working at financial institutions, in addition to having abundant insight into corporate management. Serving as Full-time Audit & Supervisory Board Member in his previous position, he is also thoroughly familiar with Audit & Supervisory Board Members' practices. The Company has judged that he is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.
	Shinkichi Matsuo	Mr. Shinkichi Matsuo is highly knowledgeable in finance and accounting as a certified public accountant and also has a wealth of experience relating to corporate management. The Company has judged that he is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.
	Takayuki Maruyama	As a lawyer, Mr. Takayuki Maruyama has expertise in corporate restructuring, business revitalization, and international contracts. The Company has judged that he is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.
	Wakako Mitani	As a lawyer, Ms. Wakako Mitani has abundant insight with regard to corporate legal affairs, centered on labor issues, in addition to governance in the medical care field and medical care-related administration. The Company has judged that she is capable of appropriately performing a management oversight role from a professional standpoint based on this knowledge and experience.

Main activities of the outside members of the Board (fiscal 2023)

Category	Name	Main activities
Outside member of the Board	Mio Minaki	Ms. Mio Minaki offered advice and recommendations on numerous occasions at meetings of the Board of Directors from an independent, objective point of view based on a wealth of experience in the legal field and professional insight into corporate legal affairs. In her capacity as a member of the Nomination and Remuneration Committee, she attended all three Committee meetings and actively offered advice and recommendations in discussions about selection of candidates for members of the Board, determination of remuneration for members of the Board, identification of skills necessary for the Board, and other matters.
	Yasuyuki Sugiura	Mr. Yasuyuki Sugiura offered advice and recommendations on numerous occasions at meetings of the Board of Directors from an independent, objective point of view based on a wide range of insights obtained through a wealth of management experience and international experience at a general trading company. In his capacity as a member of the Nomination and Remuneration Committee, he attended all three Committee meetings held after he took office and actively offered advice and recommendations in discussions about selection of candidates for members of the Board, determination of remuneration for members of the Board, identification of skills necessary for the Board, and other matters.
Outside Audit & Supervisory Board member	Hideki Hayashi	Appointed on June 21, 2024.
	Shinkichi Matsuo	Mr. Shinkichi Matsuo actively expressed opinions at Audit & Supervisory Board meetings from an independent, objective point of view based on professional insight into finance and accounting accumulated over many years. In addition, he received reports from the full-time Audit & Supervisory Board members, accounting auditor, and Audit Department, and increased the effectiveness of auditing by gathering information through interviews with the president & CEO, corporate officers in charge, and corporate officers of subsidiaries. He also attended meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.
	Takayuki Maruyama	Mr. Takayuki Maruyama actively expressed opinions at Audit & Supervisory Board meetings from an independent, objective point of view based on professional insight, mainly concerning corporate restructuring and international contracts. In addition, he received reports from the full-time Audit & Supervisory Board members, accounting auditor, and Audit Department, and increased the effectiveness of auditing by gathering information through interviews with the president & CEO, corporate officers in charge, and corporate officers of subsidiaries. He also attended meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.
	Wakako Mitani	Ms. Wakako Mitani actively expressed opinions from an independent, objective point of view based on professional insight, mainly related to governance in the medical field, public health administration, and labor issues. In addition, she received reports from the full-time Audit & Supervisory Board members, accounting auditor, and Audit Department and increased the effectiveness of auditing by gathering information through interviews with the president & CEO, corporate officers in charge, and corporate officers of subsidiaries. She also attended meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.

Board of Directors' effectiveness analysis and evaluation

At Seikagaku, a meeting of outside officers, comprising the outside members of the Board and outside Audit & Supervisory Board members, analyzes and evaluates the effectiveness of the Board of Directors on the basis of the content of a questionnaire survey conducted prior to the evaluation and reports the results of evaluation and points for improvement to the Board.

The evaluation for fiscal 2023 confirmed that decision-making on important matters and oversight of business execution functioned properly and that effectiveness of the Board of Directors was sufficiently ensured by continuing to provide advance explanations concerning important Board meeting agenda items and explanations of the proceedings of the Management Committee and other internal organizations and by having addressed issues from the previous fiscal year, such as holding an outside officers meeting on the subject of Seikagaku's sustainability initiatives.

To help activate deliberation, Seikagaku provides opportunities for sharing management issues and other matters with the outside officers and as a rule distributes materials at least three days before Board meetings to ensure sufficient time to review them beforehand.

Proposals for improvement included setting up a forum for meetings between outside officers and departments in charge concerning matters such as sustainability and the mid-term management plan and reviewing methods of sharing opinions from shareholders and investors, and the Board will respond to these proposals.

A message from an outside director



Outside Director
Mio Minaki

Demonstrating leadership in connecting an original business model to corporate value enhancement

As a pioneer in glycoconjugate research, Seikagaku has a business model centered on new drug R&D that is original and attractive, even for the pharmaceutical industry. I am aware that what is required of an outside director is leadership to ensure that the Company does not lose sight of its clear direction: namely, increasing distinctive value and contributing to solving issues facing society through its businesses while coping with changes in the business environment.

Practicing appropriate governance requires that outside directors obtain necessary information and reach a common understanding based on discussions with persons in charge of business execution. In that regard, it has been my personal experience that at Seikagaku sufficient opportunities to develop common understanding are provided through informal discussion meetings held from time to time with the persons in charge of divisions and departments, laboratory and plant inspection tours, and briefings on domestic and overseas drug price systems.

Another important role of outside directors is to more actively discuss things from a perspective different from that of inside directors with the aim of enhancing sustained growth and medium- and long-term corporate value. At the time of the previous Board of Directors' effectiveness evaluation, it was proposed that meetings attended only by outside officers be held. This proposal has been implemented since last year, and sustainability-related measures have already been discussed. I want to utilize such opportunities to deepen discussion of how Seikagaku currently publicizes its corporate value and a future vision of the Company from a longer-term perspective.

Compensation for corporate officers

At a meeting held on February 5, 2021, the Board of Directors resolved to adopt the Policy for Determining the Details of Individual Remuneration for Members of the Board and Audit & Supervisory Board Members, and Seikagaku now operates a compensation scheme in accordance with this policy. At the time of Board of Directors resolutions pertaining to compensation for corporate officers, the Board consults with the Nomination and Remuneration Committee beforehand and receives a report concerning the details of matters to be resolved.

Basic policy

The Company's basic policy on compensation for directors (excluding outside members of the Board; the same applies hereinafter in this section "Compensation for corporate officers"), is to maintain a compensation structure designed to contribute to sustained earnings improvement by increasing incentives for directors to meet the expectations of shareholders. Specifically, compensation consists of basic compensation; earnings-linked compensation and performance-linked compensation, which serve as short-term incentives; and restricted stock compensation, which serves as a long-term incentive.

Compensation for outside members of the Board and Audit & Supervisory Board members consists of basic compensation only, in view of their role of management oversight independent from business execution.

Overview of types of compensation

The following is an overview of the types of compensation.

<Basic compensation (monthly monetary compensation)>
The amount of compensation for members of the Board is determined taking into consideration the balance between the going rate, management performance, and employee salaries. The amount of compensation for outside members of the Board and Audit & Supervisory Board members is determined by making reference to the going rate.

<Performance-linked compensation (monthly monetary compensation)>
Performance-linked compensation is determined through qualitative assessment based on achievement by each director of objectives for the previous fiscal year pertaining to important measures in the mid-term management plan. Qualitative assessment according to level of achievement is a three-stage to five-stage assessment, and the amount is calculated according to each assessment by multiplying basic compensation by a predetermined coefficient.

<Earnings-linked compensation (monthly monetary compensation)>
SKK EBITDA* is used as an indicator, and the amount of compensation is determined based on SKK EBITDA from the previous fiscal year. Assessment using SKK EBITDA is a three-stage evaluation, and the amount is calculated by multiplying basic compensation by a predetermined coefficient according to the assessment of each member of the Board.

*SKK EBITDA is Seikagaku's own profit indicator consisting of operating income plus depreciation expense. The Company has selected SKK EBITDA because it considers it appropriate as a short-term incentive with respect to business performance each fiscal year. Actual SKK EBITDA for fiscal 2023 was ¥2,097 million.

<Restricted stock compensation (non-monetary compensation)>
Restricted stock compensation, which involves the granting each year at a certain time of common shares of the Company for which transfer is restricted until retirement ("restricted stock"). Compensation paid for the granting of restricted stock is a monetary claim, and the amount is calculated by multiplying the basic compensation of each member of the Board by a fixed rate for each position.

Policy on the ratio of each type of compensation for members of the Board

Compensation for members of the Board is designed so that the ratio of earnings-linked compensation increases the higher the position, taking into consideration the results of an external survey and using as a benchmark compensation levels at other companies similar in size to Seikagaku or in the same industry.

The Board of Directors receives a report from the Nomination and Remuneration Committee and reviews compensation design from time to time, taking into consideration factors such as the business environment and the Company's medium- to long-term trend in business performance.

The ratio of each type of compensation for members of the Board is roughly as follows in the case of maximum target achievement.

Basic compensation	: 70–80%
Performance-linked compensation	: 10%
Earnings-linked compensation	: 5–10%
Restricted stock compensation	: 5–10%

Method of determining compensation

By a resolution of the Board of Directors, monetary compensation for individual full-time and outside members of the Board is delegated to the Nomination and Remuneration Committee. The Committee's authority extends to determination of the amount of basic compensation, the amount of performance-linked compensation (including assessment of each director), and the amount of earnings-linked compensation. The reason for delegation of this authority is so that the Nomination and Remuneration Committee, on the basis of the expert knowledge and insights into corporate management of the outside members of the Board, to determine the amount of monetary compensation for individuals from an objective standpoint, a perspective that includes the common interests of the shareholders.

Evaluation coefficients pertaining to performance-linked compensation, as well as evaluation categories and evaluation coefficients pertaining to earnings-linked compensation, are determined beforehand by the Board of Directors, giving respect to the content of a report from the Nomination and Remuneration Committee. With regard to restricted stock compensation, a form of non-monetary compensation, the timing of payment and method of distribution of monetary compensation claims are determined by the Board of Directors, giving respect to the content of a report from the Nomination and Remuneration Committee.

Compensation for Audit & Supervisory Board members is determined through discussion among them.

Total amount of compensation for each category of officer, total amount by type of compensation, and number of relevant officers (fiscal 2023)

Officer category	Total compensation (Millions of yen)	Total by type of compensation (Millions of yen)				Number of officers
		Basic compensation	Performance-linked compensation	Earnings-linked compensation	Restricted-stock compensation	
Members of the Board (excluding outside members of the Board)	180	154	12	3	10	4
Outside members of the Board	19	19	—	—	—	2
Total	199	173	12	3	10	6
Audit & Supervisory Board members (excluding outside officers)	47	47	—	—	—	2
Outside Audit & Supervisory Board members	24	24	—	—	—	4
Total	71	71	—	—	—	6
Grand total	271	245	12	3	10	12

Notes:
1. Based on the status at the time of adjournment of the 77th Ordinary General Shareholders' Meeting, held on June 20, 2023, one retired director (excluding outside directors) and one retired outside Audit & Supervisory Board member are included in the table above.
2. The amount of pay for a member of the Board does not include the employee portion of salary of someone who is concurrently an employee and a member of the Board.
3. Stock compensation is the amount of compensation claims in respect of restricted stock compensation.
4. The total amount of compensation paid to all members of the Board was resolved at the 61st Ordinary General Shareholders' Meeting held on June 22, 2007, to be no more than ¥400 million per year (of which the outside members of the Board proportion shall be no more than ¥50 million per year). (Seven persons were eligible at the time of the shareholders' meeting resolution.) Also, the amount of compensation for separately granting restricted stock to directors (excluding outside members of the Board) was resolved at the 73rd Ordinary General Shareholders' Meeting held on June 19, 2019 to be no more than ¥50 million per year, and the total number of restricted stock shares issued or divested for granting to eligible members of the Board set at no more than 40,000 shares. Four persons were eligible at the time of the shareholders' meeting resolution.
5. The total amount of compensation paid to all Audit & Supervisory Board members was resolved at the 61st Ordinary General Shareholders' Meeting held on June 22, 2007, to be no more than ¥80 million per year. Five persons were eligible at the time of the shareholders' meeting resolution.

Measures to facilitate the exercise of voting rights

To ensure that shareholders are able to secure sufficient time for consideration of General Shareholders' Meeting proposals, the Company strives for early sending out and disclosure of the Notice of Convocation. For the 78th General Shareholders' Meeting, held on June 21, 2024, the Company disclosed the Notice of Convocation on the Tokyo Stock Exchange, Inc. website and the Seikagaku corporate website seven days before the statutory due date (four weeks before the meeting). The Company sent out the Notice of Convocation on May 30, 2024, three weeks before the meeting.

For foreign shareholders, the Company prepares an English translation of the Notice of Convocation and posts the English version on the corporate website at the same time as the Japanese version. Furthermore, the Company has responded to the diversification of methods of exercising voting rights by adopting electronic methods, including the Electronic Voting Platform for Foreign and Institutional Investors, in addition to voting in writing.

The Company has introduced measures to help increase shareholder understanding at the General Shareholders' Meeting, such as by using video and narration to provide business reports and explanations of shareholder proposals. The Company also discloses on its website a summary of the visual content of the business report provided at the General Shareholders' Meeting.

Cross-shareholdings policy

The Company strategically holds shares of other companies only when it is deemed to contribute to the enhancement of the Company's corporate value over the medium to long term on the basis of comprehensive consideration of business strategy, business relationships, and other factors.

The Financial Asset Management Committee, comprising the members of the Board, the corporate officer in charge of administration, and the managers of the Finance & Accounting Department and Corporate Planning Department, verifies each year whether the shareholding purpose and benefits and risks associated with the holdings are appropriate, and the Board of Directors evaluates the verification results. The Company's policy is to reduce any shareholding whose holding rationale is deemed unacceptable by the Board.

The Company makes decisions regarding voting rights of cross-shareholdings from the perspective of whether the content of shareholder proposals conforms to the abovementioned shareholding policy by contributing to the enhancement of the Company's corporate value over the medium to long term. In addition, financial results and other business conditions of investee companies and careful examination of whether or not the proposals contribute to increasing the shareholder value of these companies are considered.

Policies concerning constructive dialogue with shareholders and investors

The Company places importance on constructive dialogue with shareholders and investors for the purpose of realizing sustained growth and enhancement of corporate value over the medium to long term.

The Company has named the member of the corporate officer in charge of corporate staff and personnel affairs as the officer in charge of investor relations and has assigned a person in charge of corporate communication to the Corporate Staff Department. The person in charge of corporate communication has developed a system that makes possible appropriate and fair disclosure by striving to gather and share information through the holding of regular and ad hoc meetings with the Finance & Accounting Department, the Research & Development Division, the Business Development & Marketing Division, and other interested divisions and departments.

As a rule, when the Company receives requests for interviews or other forms of dialogue, an appropriate person is selected according to the purpose and promptly responds. In fiscal 2023, the Company held 67 interviews or other interactions with shareholders and investors. The content of dialogues and opinions or requests obtained through such interactions are shared internally through reporting at meetings of the Board of Directors and Management Council as appropriate and through submission of quarterly IR activities reports to the members of the Board and managers of interested departments.

In addition, the Company holds biannual financial results briefings for institutional investors, securities analysts, and the media. The president & CEO provides a review of operations, progress in R&D, measures to improve shareholder value, and other updates. The Company also strives to provide information in a more understandable manner by posting audio files, presentation materials, etc. from the financial results briefings on the corporate website thereby enhancing content for individual investors. Furthermore, the Company follows the Fair Disclosure Rules and rigorously manages insider information and disclosure information under the provisions of the Company's Insider Trading Prevention Regulations and Disclosure Policy. Additionally, the Company designates the period from the day following the quarterly closing date until the time of the announcement of the financial results as a quiet period to prevent financial information from leaking during the preparations for the announcement. During the quiet period, Seikagaku refrains from answering questions or making comments about financial results. However, the Company responds to inquiries about information that has already been published.

Measures to achieve management mindful of capital cost and share price

The Company's capital policy is to determine the Company's cost of capital yearly and report it to the Board of Directors. The Company assesses the business potential of major investment projects based on project capital cost, and investment decisions are made by the Board of Directors.

The Company has instituted a mid-term management plan covering the four-year period beginning with the fiscal 2022. Maximizing the product value of SI-6603 (a treatment for lumbar disc herniation), is a key measure in the management plan. A Biological License Application (BLA) for SI-6603 has been accepted for filing by the U.S. Food and Drug Administration, and the Company is steadily proceeding with preparations for an early new drug application and product launch. The Company aims to increase corporate value in the medium and long term and enhance its reputation in capital markets by achieving the numerical targets for fiscal 2025, the final year of the management plan (net sales of ¥40.0 billion and operating income of ¥7.0 billion).

Materiality 4

Compliance and Risk Management

Compliance

To ensure high ethical standards across all aspects of corporate activities as required of a pharmaceutical company, Seikagaku has positioned honest and fair behavior as the basis of all activities. This involves not only complying with strict laws and regulations, but also putting into practice the principle of “Conducting oneself in a disciplined manner in accordance with morals and also courageously correcting the misdeeds of others.”

To embody these ideals, Seikagaku has instituted a compliance program (including the SKK Group Compliance Code of Conduct) based on the Creed and the Guidelines for Our Activities. To more appropriately and smoothly implement the program, Seikagaku has developed a compliance program implementation structure, established the Compliance Promotion Committee, and installed a compliance officer and compliance promotion officers. The Compliance Promotion Committee, which is chaired by the president & CEO and has the Management Committee members as its members, increases compliance effectiveness by promoting and implementing measures to increase compliance awareness on a company-wide level through an activity plan set every year.

Outline of the SKK Group Compliance Code of Conduct

As an employee of a life sciences company, each Seikagaku employee makes respect for life the primary consideration and behaves on the basis of high corporate ethical standards that earn the trust and support of society.

Diagram of Implementation Structure



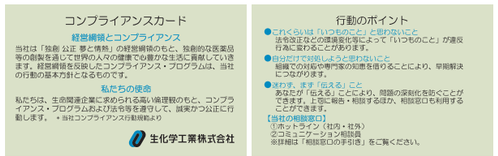
<Role of Compliance Promotion Committee>
The committee approves measures to promote compliance in accordance with the Compliance Program and supervises the status of their implementation.

<Role of Compliance Promotion Officers>
They are responsible for implementing the Compliance Program in their respective divisions, carrying out self-inspections, and also implementing the resolutions of the Compliance Promotion Committee.

For details on the Compliance Program, please visit the Seikagaku corporate website.
https://www.seikagaku.co.jp/en/corporate/compliance.html

Compliance promotion activities

To ensure rigorous implementation of the Compliance Program, we have distributed to all employees the Compliance Program Handbook, which sets down compliance standards (including the Code of Conduct) and procedures, and the Compliance Card, which summarizes key points of employee behavior. Also, to increase the effectiveness of the Compliance Program, Seikagaku engages in internal education and awareness activities, such as periodic training on the SKK Group Compliance Code of Conduct and training on compliance topics that vary each fiscal year, and continuously strives to foster compliance awareness.



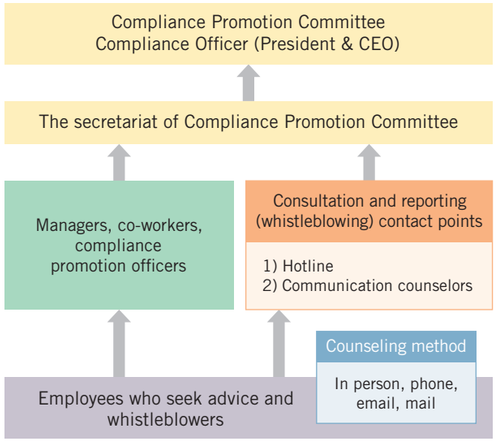
Compliance Card

Whistleblower system

The Compliance Program is closely connected to appropriate business execution as well as maintenance of a worker-friendly workplace environment for employees.

In the interest of early detection of Compliance Program violations and suspected violations and the resolution of problems, Seikagaku has set up a compliance hotline (an internal consultation and whistleblowing contact point) as well as a communications counseling system (male and female staff appointed at each business site) to respond to internal communication issues. Furthermore, by establishing multiple internal and external consultation contact points, such as utilization of an external whistleblowing channel, Seikagaku has put in place an environment that enables persons seeking advice to use the contact point that makes them feel most at ease, depending on the problems they face or individual circumstances. To ensure awareness and penetration of the whistleblowing system, Seikagaku also engages in awareness activities, such as distributing to all employees a wallet-sized card containing hotline information.

Consultation and Reporting Route



Protection of employees who seek advice and whistleblowers

Seikagaku gives the highest priority to protecting the confidentiality and privacy of employees who seek advice and to whistleblowers. Information about employees who seek advice, whistleblowers, and those involved shall be disclosed on a need-to-know basis and their privacy and anonymity shall be protected. Seikagaku stipulates in its internal regulations that sufficient care must be taken to ensure that whistleblowers and those who have cooperated with investigations do not suffer any detriment as a result of speaking out.

Monitoring of selling and information provision activities

Laws and regulations, as well as self-regulation by industry associations, are becoming increasingly rigorous as compliance awareness in society grows. Seikagaku has established the Marketing Activity Supervision Unit to provide correct, scientifically accurate information related to product safety and efficacy. This unit ensures compliance with regulations by examining presentation materials, etc., and monitoring information provision activities.

Risk management

Seikagaku has established Corporate Risk Management Regulations and developed a structure for monitoring and managing risks related to the execution of business operations. The President has overall responsibility for managing corporate risk, while officers and general managers are responsible for properly managing risks and preventing risks from being realized in the operations under their jurisdiction.

Business risks are described on our website
https://www.seikagaku.co.jp/en/ir/management/risk.html

Risk management structure

Seikagaku has also established a Risk Management Committee, which deliberates and establishes company-wide risk management policies and preventive measures. When a new major risk emerges, the Risk Management Committee is also responsible for setting up a task force immediately and implementing countermeasures to minimize any damage.
The occurrence of an emergency, the establishment of a task force, the response policy, and the implemented response measures are reported to the Board of Directors.

Risk Management Structure



Consolidated 10-year Summary

(Millions of yen / %)

	2015/3	2016/3	2017/3	2018/3	2019/3	2020/3	2021/3	2022/3	2023/3	2024/3
Net Sales*1	27,589	29,211	28,321	31,434	27,559	29,206	27,734	34,851	33,456	36,213
Overseas Sales*1	9,753	11,530	11,319	12,281	12,098	13,205	14,361	17,918	20,048	22,114
Cost of Sales	12,130	12,871	13,247	13,008	13,114	12,513	12,112	14,323	15,432	19,336
Selling, General and Administrative Expenses*1	12,833	13,833	13,113	13,872	12,727	12,796	13,372	16,033	15,910	16,444
R&D Expenses	8,146	8,649	7,834	8,408	7,148	6,877	7,209	9,005	7,951	7,484
Operating Income*1	2,624	2,506	1,960	4,552	1,718	3,896	2,248	4,495	2,114	433
Ordinary Income	4,008	3,500	2,477	5,327	2,859	3,981	3,024	5,395	3,069	1,691
Net Income	3,650	2,578	1,787	3,922	2,244	(10,839)	4,262	3,733	2,236	2,186
Total Equity	70,410	69,815	70,646	73,945	73,036	59,767	63,604	66,340	67,216	72,282
Total Assets	80,889	80,218	80,048	84,098	80,238	68,746	69,915	75,244	75,625	81,795
Overseas Sales Ratio (Excluding Royalty Income)*1	34.8	38.7	38.7	41.5	43.8	46.8	50.5	56.6	59.9	60.3
Cost of Sales Ratio (Excluding Royalty Income)*1	44.4	44.6	47.9	46.0	48.9	45.9	44.8	46.4	46.1	54.4
Selling, General and Administrative Expenses Ratio*1	46.5	47.4	46.3	44.1	46.2	43.8	48.2	46.0	47.6	45.4
R&D Expenses Ratio (Excluding Royalty Income)*1	29.8	30.0	28.3	29.7	26.7	25.2	26.7	29.2	23.8	21.1
Operating Income Ratio*1	9.5	8.6	6.9	14.5	6.2	13.3	8.1	12.9	6.3	1.2
Ordinary Income Ratio*1	14.5	12.0	8.7	16.9	10.4	13.6	10.9	15.5	9.2	4.7
Net Income Ratio	13.2	8.8	6.3	12.5	8.1	—	15.4	10.7	6.7	6.0
Return on Equity (ROE)*2	5.4	3.7	2.5	5.4	3.1	—	6.9	5.7	3.3	3.1
Return on Assets (ROA)*2	5.2	4.3	3.1	6.5	3.5	5.3	4.4	7.4	4.1	2.1
Turnover of Total Assets*2	0.38	0.38	0.37	0.37	0.35	0.39	0.40	0.48	0.44	0.46
Shareholders' Equity Ratio	87.0	87.0	88.3	87.9	91.0	86.9	91.0	88.2	88.9	88.4
Number of R&D Personnel	216	221	222	233	233	242	231	223	196	195
R&D Personnel Ratio	33.3	33.3	32.3	32.5	31.3	27.9	25.3	23.8	20.0	19.7
Number of Employees	649	663	687	718	744	868	913	937	976*3	988*3
Amount of Capital Expenditure	2,095	1,975	1,173	1,591	1,310	2,109	2,127	2,194	2,091	4,861
Depreciation and Amortization	2,610	3,191	2,920	2,925	2,902	1,778	808	1,051	1,327	1,664
Net Income per Share	64.27	45.39	31.55	69.30	39.76	(192.15)	75.54	66.32	40.49	40.08
Total Equity per Share	1,239.51	1,229.05	1,248.07	1,306.37	1,294.88	1,059.40	1,127.14	1,179.46	1,232.41	1,324.82
Dividends per Share	26.00	26.00	31.00*4	26.00	26.00	26.00	24.00*5	30.00*6	26.00	26.00
Dividend Payout Ratio	40.5	57.3	98.3	37.5	65.4	—	31.8	45.2	64.2	64.9
Dividends as a Percentage of Total Equity (DOE)	2.2	2.1	2.5	2.0	2.0	2.2	2.2	2.6	2.2	2.0

*1 New revenue recognition standard has been applied retroactively to fiscal 2013-fiscal 2020 figures.
*2 Total Equity and Total Assets are average amounts of the numbers for the end of previous FY and the end of current FY, respectively.
*3 Excluding executive vice presidents.
*4 Including a 70th anniversary commemorative dividend of ¥5 per share.
*5 Including a JOYCLU approval commemorative dividend of ¥4 per share.
*6 Including a JOYCLU launch special dividend of ¥10 per share.

Review of Operations (April 1, 2023–March 31, 2024)

Overall net sales and income

In the fiscal year ended March 31, 2024 (fiscal 2023), net sales were ¥36,213 million, up 8.2% year on year. The increase is attributable to sales volume growth from domestic pharmaceuticals and from ARTZ for China and other overseas pharmaceuticals, coupled with an increase in royalty income, which offset lower sales volume of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market, and a decline in overseas sales in the LAL business.

Operating income fell 79.5% year on year to ¥433 million, a decline mainly attributable to an increase in the cost of sales ratio due to an inventory write-down, bringing forward of facilities maintenance to strengthen the production system, and higher expenses in the LAL business. Ordinary income fell 44.9% year on year to ¥1,691 million, while net income attributable to owners of parent fell 2.2% to ¥2,186 million.

(Millions of yen)

	2023/3	2024/3	Year on Year
Net Sales	33,456	36,213	8.2%
Operating Income	2,114	433	−79.5%
Ordinary Income	3,069	1,691	−44.9%
Net Income	2,236	2,186	−2.2%
R&D Expenses	7,951	7,484	−5.9%

Net sales by segment

(Millions of yen)

Sales by Segment	2023/3	2024/3	Year on Year
Pharmaceuticals Business	22,723	25,942	14.2%
Domestic Pharmaceuticals	11,271	12,100	7.3%
Overseas Pharmaceuticals	8,534	10,059	17.9%
Bulk Products and CDMO	2,916	3,083	5.7%
Royalty Income	1	699	—%
LAL Business	10,732	10,271	−4.3%
Total	33,456	36,213	8.2%
(Overseas Sales)	20,048	22,114	17.9%

Pharmaceuticals business

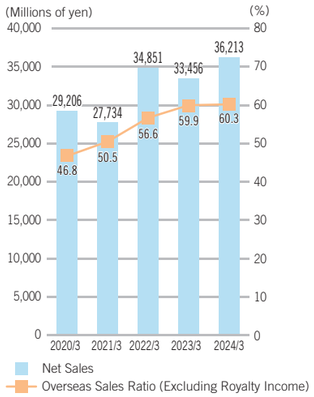
The Pharmaceuticals business is the core business of our company, which manufactures and sells pharmaceuticals, medical devices, and bulk products based on glycoconjugates such as hyaluronic acid. In the Pharmaceuticals business, net sales increased 14.2% year on year to ¥25,942 million, accounting for 71.6% of total sales.

Domestic Pharmaceuticals (¥12,100 million, up 7.3% year on year)

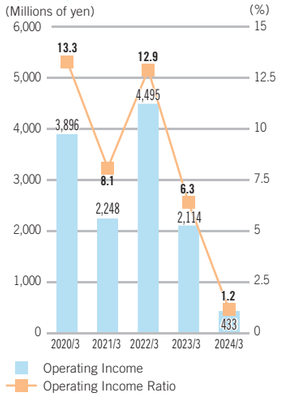
Revenue from domestic pharmaceuticals rose 7.3% year on year, mainly due to increases in the Company's sales of ARTZ, a joint function improvement agent for knee osteoarthritis, and the OPEGAN series of ophthalmic viscoelastic devices.

Deliveries to medical institutions of ARTZ increased year on year thanks to continued switching from competing products. This growth led to an increase in the Company's sales, despite the impact of National Health Insurance (NHI) drug price reductions.

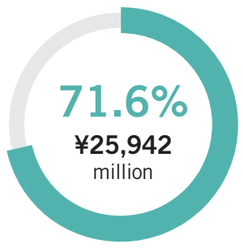
Net Sales and Overseas Sales Ratio



Operating Income and Operating Income Ratio



Pharmaceuticals Business Sales Composition



Deliveries to medical institutions of the OPEGAN series increased year on year, reflecting a continued gradual market growth trend accompanying population aging. This brought an increase in the Company's sales, despite the impact of NHI drug price reductions.

In the results for other products, the Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, increased, reflecting a sales partner inventory adjustment. The Company's sales of HERNICORE, a treatment for lumbar disc herniation, remained at the prior-year level.

The Company's sales of the joint function improvement agent JOYCLU declined year on year. The Company issued a Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) concerning JOYCLU on June 1, 2021 and is continuing cooperative efforts with sales partner Ono Pharmaceutical Co., Ltd. to gather side effects reports and other information and provide safety-related information.

Overseas Pharmaceuticals (¥10,059 million, up 17.9% year on year)

Revenue from overseas pharmaceuticals rose 17.9% year on year thanks mainly to increases in the Company's sales of ARTZ for China and SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market, despite lower sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis for the U.S. market.

Local sales volume and the Company's sales of Gel-One declined year on year, despite a gradual trend toward recovery from the impact of an insurance reimbursement system change implemented in July 2022.

Local sales volume in the U.S. of SUPARTZ FX rose due to increased preference for a stable product subject to minimal price fluctuation against the backdrop of an insurance reimbursement system change. The Company's sales rose because of the combined impact of a shipping schedule adjustment and yen depreciation.

Local sales volume of ARTZ for China rose, reflecting recovery in the patient consultation rate as the impact of COVID-19 dissipated. In addition, the Company's sales rose sharply year on year, reflecting a rebound following lower-than-normal sales in the first quarter of fiscal 2022 when a packaging material change led to an absence of shipments and the bringing forward of product shipments originally scheduled for fiscal 2024.

Bulk Products and Contract Development and Manufacturing Organization (¥3,083 million, up 5.7% year on year)

Sales increased due to higher sales of contract development and manufacturing and other services of overseas subsidiary Dalton Chemical Laboratories, Inc. coupled with yen depreciation.

Royalty Income (¥699 million, —)

Royalty income has significantly increased. Beginning in fiscal 2021, royalty income has been reclassified from non-operating income to net sales.

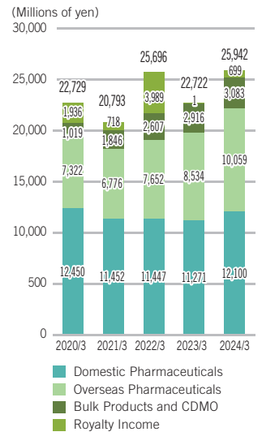
LAL business

We manufacture and sell endotoxin-detecting reagents used in the quality control of pharmaceuticals and medical devices in Japan and overseas. Net sales of LAL business for the fiscal year under review were ¥10,271 million, down 4.3% from the previous fiscal year.

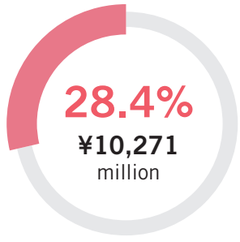
LAL Business

Although domestic sales remained at the same level as the previous fiscal year, sales at the overseas subsidiary, Associates of Cape Cod, Inc., declined due to the conclusion of special demand brought about by the spread of COVID-19.

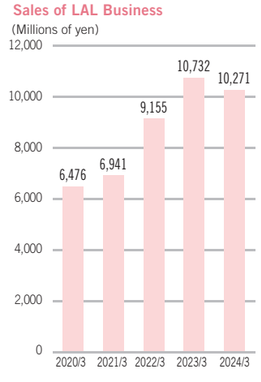
Sales of Pharmaceuticals Business



LAL Business Sales Composition

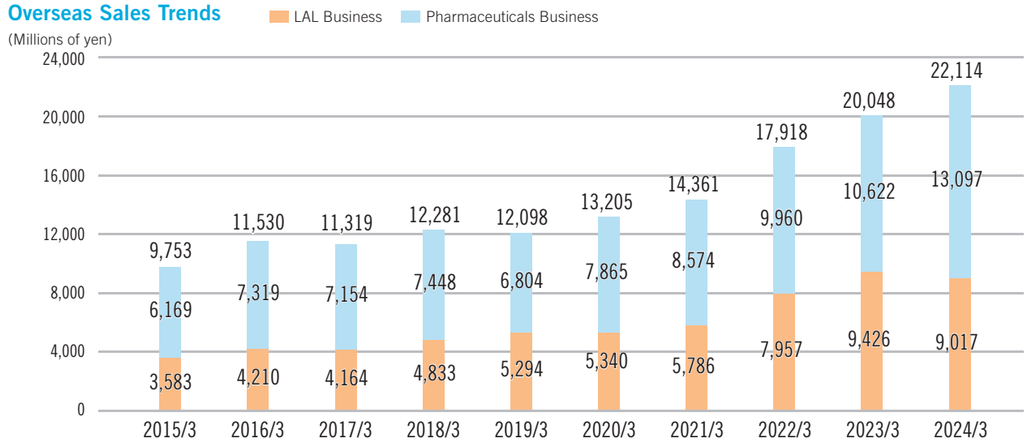


Sales of LAL Business

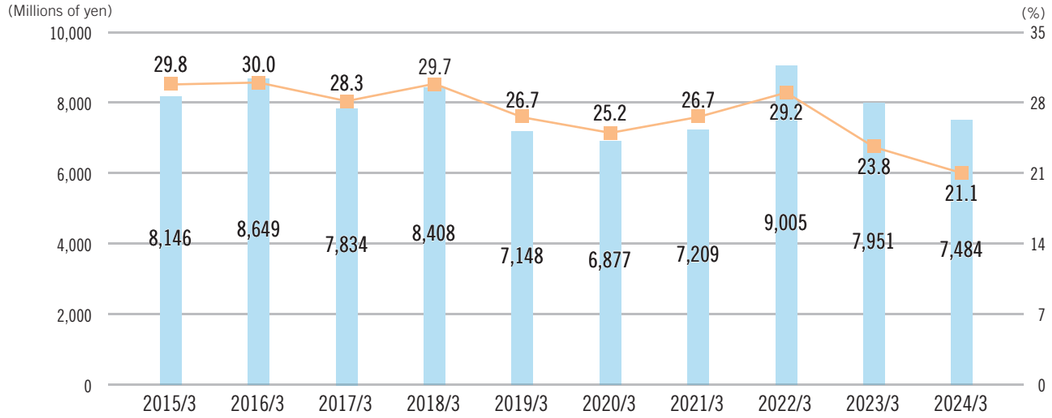


Financial/Non-financial Highlights

Overseas Sales Trends

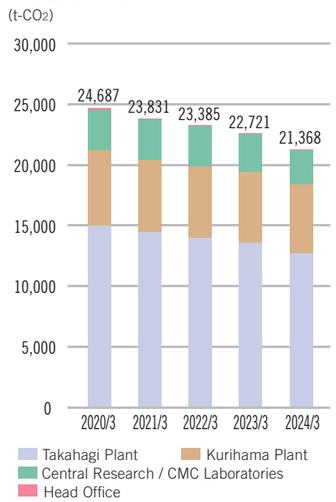


R&D Expense Trends

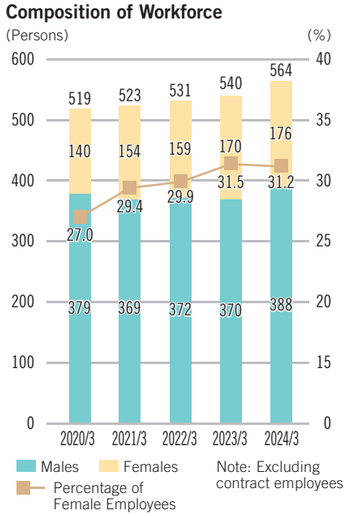


Non-financial Highlights (Non-consolidated Basis)

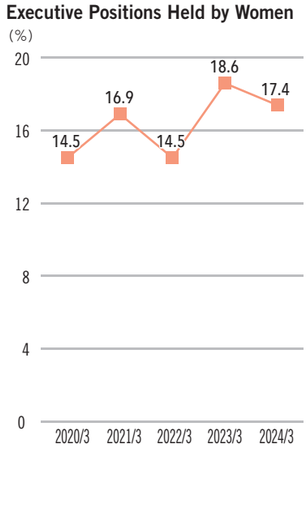
CO_2 Emissions



Composition of Workforce



Executive Positions Held by Women



Overseas Subsidiaries

Associates of Cape Cod, Inc. (Massachusetts, USA)

Associates of Cape Cod, Inc. (ACC), a wholly owned subsidiary of Seikagaku, was the first FDA-licensed LAL manufacturer in the world.

It was established in 1974, became a Seikagaku subsidiary in 1997, and currently plays a central role in the global Bacterial Endotoxin Testing and clinical glucan detection sectors. ACC employs approximately 290 employees and has operations in the U.K. and Germany.

ACC's reagent and diagnostics production facility, located at their campus in Falmouth Technology Park in Massachusetts, is vertically integrated with an end-to-end manufacturing operation that extends from harvesting horseshoe crab blood cells, a reagent raw material, to manufacturing, testing, packaging/labeling, and distributing endotoxin and glucan in vitro diagnostic agents. From the perspective of promoting the appropriate use of natural resources and biodiversity, we have also recently focused on the manufacture and sale of gene-recombinant endotoxin-detecting reagents (see P07) without the blood harvested from horseshoe crabs.

Corporate Outline (As of March 31, 2024)

Paid-in Capital	$2,080
Ownership Ratio	100%
Business	Manufacturing and sales of reagents and diagnostics
URL	https://www.acciusa.com



Dalton Chemical Laboratories, Inc. (Ontario, Canada)

Dalton Chemical Laboratories, Inc., (DCL) which became a Seikagaku subsidiary in March 2020, is a company that provides services including contract development and manufacturing (CDMO) services for pharmaceutical companies, such as manufacturing of chemical synthetics and pharmaceutical ingredients as well as manufacturing process development. DCL was established in 1986 and has a U.S. and Canadian GMP*1–compliant manufacturing site for pharmaceuticals and other products in Ontario, Canada. DCL currently has approximately 140 employees.

Seikagaku will utilize DCL's chemical synthesis technologies and expertise in manufacturing process development in its new drug development. In addition, Seikagaku will transfer the manufacturing of investigational drugs and some Seikagaku products to DCL, as well as switch from the outsourced manufacturing of chemical synthetics used for research and other purposes to in-house production by DCL.

*1 GMP: Good Manufacturing Practice
Standards for manufacturing control and quality control in manufacturing.

Corporate Outline (As of March 31, 2024)

Paid-in Capital	CAD 49,800 thousand
Ownership Ratio	100%*2
Business	CDMO
URL	https://www.dalton.com/



*2 DCL is a wholly owned subsidiary of SKK CANADA ENTERPRISES CORPORATION, an intermediate holding company established in Canada by Seikagaku.

Corporate Data

Overview (As of March 31, 2024)

Company Name	SEIKAGAKU CORPORATION
President	Ken Mizutani
Establishment	June 2, 1947
Business Activities	Manufacturing and sales of pharmaceuticals and medical devices specifically related to glycoconjugates
Fiscal Year	April 1 to March 31
Stock Exchange Listing	Tokyo Stock Exchange, Prime Market (Stock code: 4548)
URL	https://www.seikagaku.co.jp/en/
Number of Employees	988 (Consolidated/Excluding executive vice presidents)
Paid-in Capital	¥3,840 million
Net Sales	¥36,213 million (As of March 31, 2024)

Organization Chart

Please refer to our website for the organizational chart.

https://www.seikagaku.co.jp/en/corporate/organization.html

External Evaluation

EcoVadis provides a platform for the holistic evaluation of corporate social responsibility and sustainability.
We were awarded a Silver Medal (top 25%) in the 2023 EcoVadis evaluation.

EcoVadis: https://ecovadis.com/

We earned a "B" score from CDP in the 2023 Climate Change evaluation.
CDP is a not-for-profit charity that runs a global disclosure system for companies and municipalities seeking to manage their environmental impacts.

CDP: https://www.cdp.net/en

Locations

Head Office	Marunouchi Center Building 6-1, Marunouchi 1-chome Chiyoda-ku Tokyo 100-0005, Japan Tel: (81) 3-5220-8950
Central Research Laboratory/ CMC Laboratory	1253, Tateno 3-chome Higashiyamato-shi Tokyo 207-0021, Japan Tel: (81) 42-563-5811
Kurihama Plant	3-1, Kurihama 9-chome Yokosuka-shi Kanagawa 239-0831, Japan Tel: (81) 46-835-3311
Takahagi Plant	258-5, Aza-Matsukubo Oaza-Akahama Takahagi-shi Ibaraki 318-0001, Japan Tel: (81) 293-23-1181

Major Subsidiaries

ASSOCIATES OF CAPE COD, INC.

124 Bernard E. Saint Jean Drive, East Falmouth
MA 02536-4445 U.S.A.
Tel: (1) 508-540-3444

DALTON CHEMICAL LABORATORIES, INC.

349 Wildcat Rd. Toronto, ON M3J 2S3
CANADA
Tel: (1) 416-661-2102 / (1) 800-567-5060

Stock Information

Stock Information (As of March 31, 2024)

Shares per Unit	100
Authorized Shares	234,000,000
Authorized Outstanding Shares	56,814,093
Number of Shareholders	10,878
General Shareholders' Meeting	June
Date of Record for Shareholders Eligible to Receive Dividends	March 31

Shareholder Registry Administrator

Mitsubishi UFJ Trust and Banking Corporation

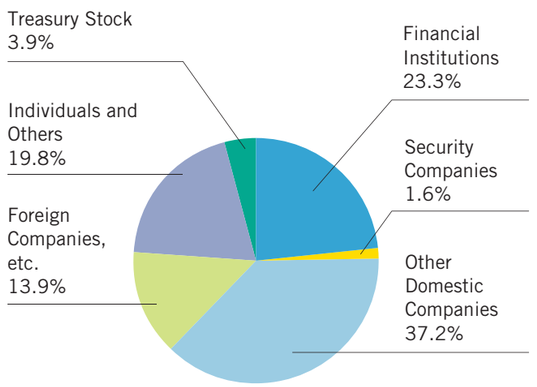
<Contact>
Mitsubishi UFJ Trust and Banking Corporation
Securities Agency Division
PO Box 29, New Tokyo Post Office, Tokyo 137-8081
Tel: 0120-232-711 (Domestic toll-free)

Major Shareholders (As of March 31, 2024)

	Name of Shareholders	Number of Shares Held (Thousands of Shares)	Percentage of Outstanding Shares (%)
1	Shingyo KK	7,843	14.4
2	KK Kaiseisha	7,293	13.4
3	The Master Trust Bank of Japan, Ltd. (Trust account)	6,440	11.8
4	Custody Bank of Japan, Ltd. as trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co., Ltd.	1,573	2.9
5	MUFG Bank, Ltd.	1,536	2.8
6	The Bank of New York Mellon (International) Limited 131800	1,420	2.6
7	Kaken Pharmaceutical Co., Ltd.	1,207	2.2
8	Custody Bank of Japan, Ltd. (Trust account)	1,054	1.9
9	Mizutani Foundation for Glycoscience	828	1.5
10	Meiji Yasuda Life Insurance Company	688	1.3

Notes: 1 As of March 31, 2024, the Company holds 2,253 thousand shares of treasury stock, which are not included in the above.
2 The treasury stock (2,253 thousand shares) is excluded from the calculations of the percentages above.

Breakdown of Shareholders by Type (As of March 31, 2024)



Corporate Logo

The main motif of Seikagaku's corporate logo is a chain, which symbolizes our decades-long commitment to sugar chain R&D. The closely interlocked links represent the strong bonds that exist between science and industry, between people and people, and between a rich natural environment and an enriching life. The links also symbolize Seikagaku's emphasis on partnership with society.

The overall shape of the logo as an oval stretched toward the upper right represents Seikagaku's corporate stance of aiming for infinite growth.

The blue brand color in the corporate logo symbolizes creativity and innovation, while the black projects an impression of strength.

SEIKAGAKU CORPORATION

Marunouchi Center Building
6-1, Marunouchi 1-chome, Chiyoda-ku
Tokyo 100-0005, Japan
TEL: (81) 3-5220-8950
FAX: (81) 3-5220-8951
URL: https://www.seikagaku.co.jp/en/

