



**SEIKAGAKU**  
**CORPORATE**  
**REPORT**  
**2021**



INNOVATIVE  
THINKING



**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 25% to 30% of net sales, and that 40%\* of our employees are involved in R&D.

\*Non-consolidated base

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 2021 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 2020 (April 1, 2020–March 31, 2021), but it also includes references to activities in fiscal 2021.

# 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® is scheduled for delisting 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

**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.

**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 (now the JASDAQ).

**1997**

Seikagaku Corporation acquires Associates of Cape Cod, Inc. (U.S.A.).



**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).

**2020**

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



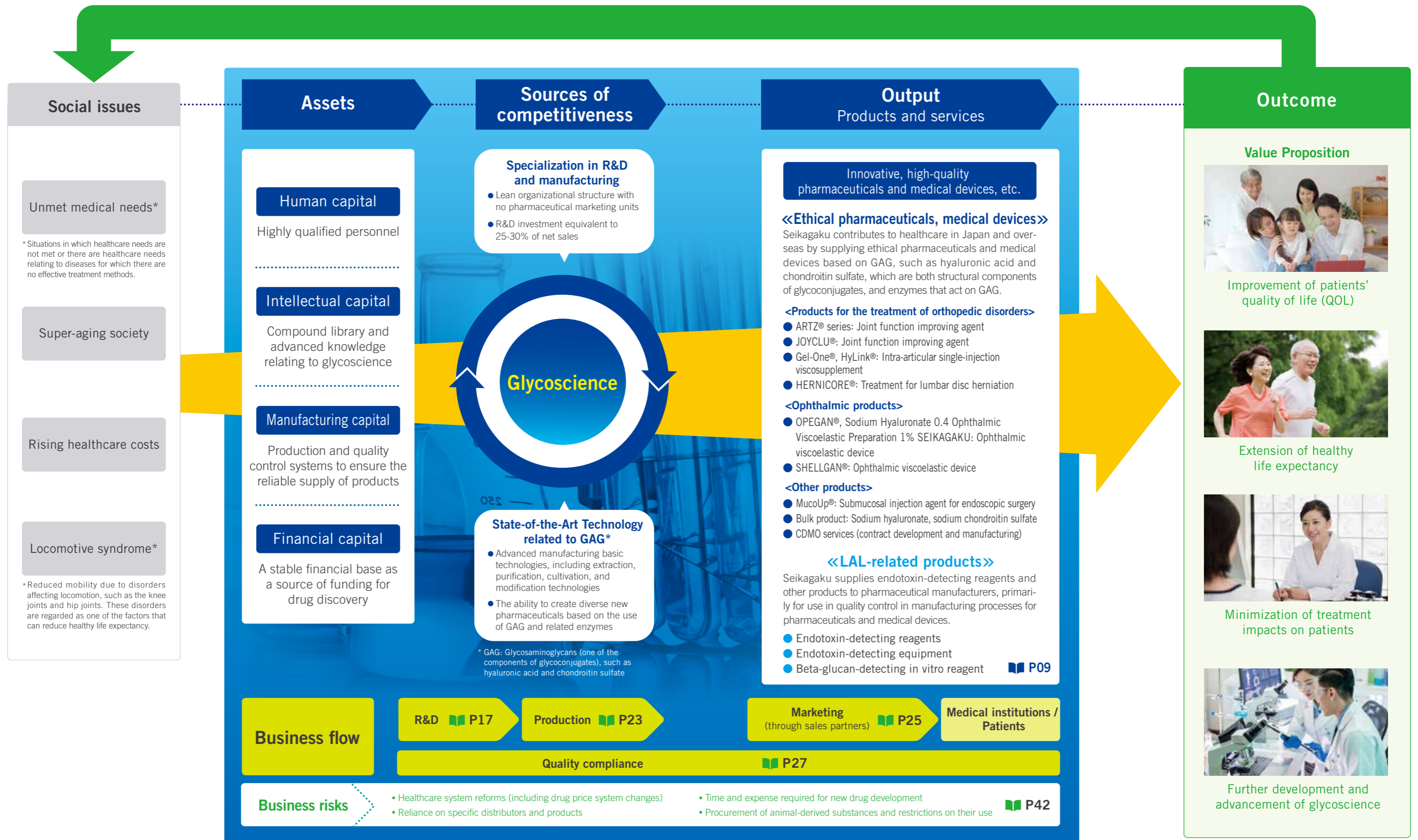
\* CDMO: Contract Development and Manufacturing Organization  
A business that supplies comprehensive services in drug development and manufacturing to pharmaceutical companies, including contract drug manufacturing, pharmaceutical formulation planning at the development stage, manufacturing of investigational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

Net Sales (Millions of yen)

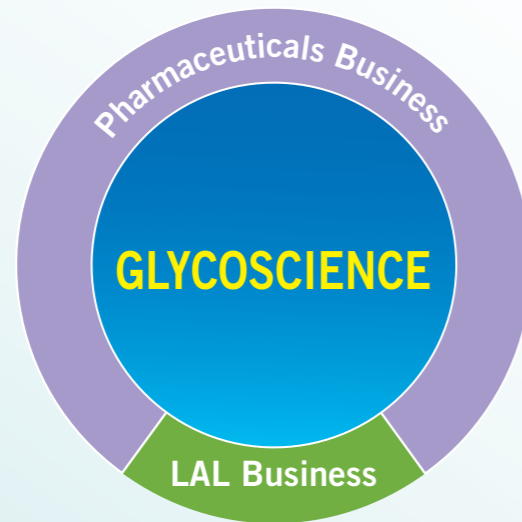


# Innovating Novel Contributions and Approaches

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.



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 amoebocyte 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. It was launched in April 2021 by overseas subsidiary Associates of Cape Cod, Inc. and introduced in Japan in May.

#### ● 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. 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. When administered directly into the joint cavity, ARTZ Dispo is expected to reduce pain and inflammation. It 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 been filled with solution.

\*2 Scheduled for delisting from the NHI drug price standard on March 31, 2022.

#### ● JOYCLU®

JOYCLU, a formulation in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound, is a joint function improving agent launched in May 2021. 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.

#### ● Gel-One®, HyLink®

Gel-One is an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, which contains cross-linked hyaluronate hydrogel as its main ingredient, originally developed for the U.S. market. Administration of only 3mL provides long-lasting benefits. In March 2019, Seikagaku launched this product in Italy with its brand name "HyLink." Seikagaku is expanding the sales of this unique product with multi-branding strategy. It was launched in Taiwan in August 2021.



ARTZ Dispo®



SUPARTZ FX®



JOYCLU®



Gel-One®



HERNICORE®

### Treatment for Lumbar Disc Herniation

#### ● HERNICORE®

HERNICORE, which contains an enzyme named "condoliase" as its active pharmaceutical ingredient, is Japan's first product for the treatment of lumbar disc herniation (intradiscal enzyme injection therapy). 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.

### 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 excellent viscoelastic properties of hyaluronic acid. By injecting MucoUp into the submucosa beneath the lesion during the endoscopic resection of tumors in the gastrointestinal tract such as esophagus, stomach and large intestine, it 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

### CDMO

#### ● CDMO services (contract development and manufacturing)

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



We will work to further solidify the profit foundation in the final year of the mid-term management plan by steadily implementing the important measures set forth in the plan.

*President & CEO Ken Mizutani*

### The strategic positioning of the current mid-term management plan

Seikagaku Corporation has instituted a mid-term management plan (please refer to page 14) in which we have positioned the three-year period beginning in the fiscal year ended March 31, 2020 (fiscal 2019) as a time for solidifying the profit foundation to return Seikagaku to a growth trajectory. We have identified three important measures in the plan: 1) Accelerating new drug discovery to become the pillar of new profits, 2) Solidifying the profit foundation through market expansion of new products, and 3) Productivity improvement reforms.

Seikagaku faces a difficult business environment. Our mainstay products have been heavily affected by NHI drug price reductions in Japan resulting from a drastic reform of the drug price system, and in the U.S. osteoarthritis market, new products from competitors have intensified competition. In the area of new drug development, even as the entire industry faces the challenges of escalating R&D expenses and depletion of seeds for new drug development, new therapeutic techniques, such as regenerative medicine, continue to emerge, and diversification of drug discovery modalities is progressing. To respond to these

rapidly evolving challenges, we are working to build a strong profit foundation to support Seikagaku's future growth by moving forward with these measures with a sense of alacrity and unconstrained by existing frameworks.

### Progress of the mid-term management plan

Although fiscal 2020, the second year of the mid-term management plan, was a year fraught with uncertainties such as the spread of COVID-19 infections, we were able to achieve a certain measure of positive results.

"Accelerating new drug discovery to become the pillar of new profits" is the first of the three important measures set out in the management plan. Seikagaku obtained manufacturing and marketing approval in Japan for the joint function improvement agent JOYCLU (development code: SI-613) for the indication of osteoarthritis (knee joint and hip joint) in March 2021 and began distribution of JOYCLU through sales partner Ono Pharmaceutical Co., Ltd. in May. Subject enrollment in a Phase I/II clinical study in the U.S. of SI-722, a treatment for interstitial cystitis, was completed in January 2021. In tolerability evaluation, a primary objective of the study, the tolerability of SI-722 was confirmed, and we are currently considering

the next-phase study.

The second important measure is "Solidifying the profit structure through market expansion of new products." We concluded two agreements with Eisai Co., Ltd. for SI-613, an osteoarthritis treatment: an agreement concerning co-development and a marketing alliance in China in April 2020 and an agreement concerning a marketing alliance in South Korea in September 2020. Furthermore, in April 2021 overseas subsidiary Associates of Cape Cod, Inc. ("ACC") launched PyroSmart NextGen recombinant LAL reagent, an endotoxin-detecting reagent manufactured using recombinant technology resulting from research and development conducted over many years at Seikagaku. (Please refer to page 9.) Seikagaku launched PyroSmart NextGen in Japan in May, taking a first step toward new market expansion.

As part of "Productivity improvement reforms," the third important measure in the management plan, we are proceeding with the transfer of some manufacturing responsibilities to Dalton Chemical Laboratories, Inc. (Dalton), which was acquired and made a subsidiary in March 2020. We will continue our pursuit of production optimization and efficiency improvement through sequential switching from outsourced manufacturing of chemical synthetics to in-house production and the transfer of manufacturing of investigational drugs and some Seikagaku products to Dalton. Furthermore, the Company is implementing organizational moves designed to maximize the value of resources, such as appointing and training young employees to be research team leaders and persons in charge of various production activities. We are also proceeding with a complete overhaul of personnel systems for the purpose of organizational reform and aim to apply revised systems during the period of the current mid-term management plan.

In fiscal 2021, the third and final year of the current mid-term management plan, we will further strengthen initiatives to implement the three important measures in the plan in order to solidify the profit foundation in preparation for the next management plan.

### Joint function improvement agent JOYCLU

On June 1, 2021, Seikagaku issued a Dear Healthcare Professionals Letter of Rapid Safety Communication (Blue Letter) concerning JOYCLU, a product launched in May 2021, in response to multiple reports of shock or anaphylaxis following administration. Although the Important Side Effects section of the JOYCLU package insert calls attention to the risk of shock and anaphylaxis, we issued the Blue Letter for the purpose of increasing awareness of these side effects among healthcare professionals and ensuring patient safety by promoting appropriate treatment and measures.

Seikagaku considers the multiple reports of side effects among patients treated with JOYCLU a matter to be addressed with the highest priority. We will continue coop-

erative efforts with sales partner Ono Pharmaceutical Co., Ltd. to proactively gather side effect reports and other information and provide safety information and will strive for early identification of the cause of the side effects.

Furthermore, we will consider how to move forward with SI-613, which is currently under development in the U.S., China, and South Korea, while carefully examining the JOYCLU situation in Japan and its impact.

### The impact of COVID-19 infections on Seikagaku

In fiscal 2020, the spread of COVID-19 infections caused enormous changes in the business and work environments. Seikagaku is putting in place a system to ensure continuity of business while striving to prevent the infection of our employees and their family members by implementing measures to adapt to new ways of working, such as introduction of work from home and development of the IT environment. The Production Division is continuing production in order to fulfill our responsibility of ensuring a stable supply of Seikagaku pharmaceuticals and medical devices, while placing the highest priority on employee safety.

We will continue to swiftly gather information and promptly respond to circumstances as they arise in order to fulfill our responsibility to society and duty to ensure a stable supply of products as a pharmaceutical company.

### To our shareholders and other stakeholders

When formulating the mid-term management plan, we defined the vision Seikagaku will pursue from a medium- to long-term perspective as "A company that is valued by the world through its innovative drug discovery." Seikagaku has unique knowledge and expertise in the field of glycoscience cultivated over many years, and we consider it our mission to utilize these strengths to continuously create innovative new drugs. We aim to enhance our value to society as a pharmaceutical company by contributing to the health and well-being of people around the world through the wider provision on a global scale of new pharmaceuticals that patients truly need.

We will also strive to strengthen corporate governance on the basis of high ethical standards by rigorously practicing honest corporate activities and ensuring management transparency.

We request the continued understanding and support of our shareholders and other stakeholders in the coming years.

**Basic policy on profit distributions**

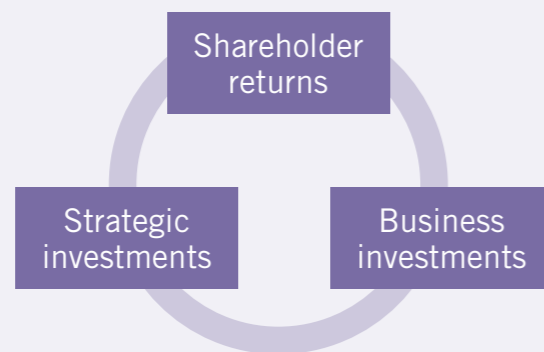
As a means of ensuring sustainable profit growth and improving corporate value, Seikagaku believes in the sharing of profits with its shareholders.

Seikagaku considers the return of profits to shareholders to be an important management challenge and has made paying dividends linked to business performance a basic policy. Seikagaku will also consider the purchase of treasury stock as appropriate, taking into consideration future business expansion and the total return ratio.

To strengthen the profit foundation and improve capital efficiency, Seikagaku will make business investments in the areas of R&D and production system development for the purpose of creating new value and also actively pursue strategic investments with prospects for future growth and synergistic effects.

Looking at shareholder returns during the period of the current mid-term management plan, Seikagaku paid annual dividends of ¥26 per share for fiscal 2019 and ¥24 per share for fiscal 2020. We will strive to maintain consistent shareholder returns in fiscal 2021, aiming for a dividend payout ratio of 50%, taking into consideration business profits and other factors.

Also, Seikagaku acquired 200,000 shares of treasury stock at an acquisition cost of ¥221 million in July 2021.



<b>Shareholder returns</b>	<ul style="list-style-type: none"> <li>• Aiming for a 50% dividend payout after considering business profits etc.</li> <li>• Examining the purchase of company treasury stock when appropriate</li> </ul>
<b>Business investments</b>	<ul style="list-style-type: none"> <li>• Investing efficiently in R&amp;D and production facilities etc. for creating new value</li> </ul>
<b>Strategic investments</b>	<ul style="list-style-type: none"> <li>• Carrying out initiatives for strategic investments with prospects for future growth and synergy effects</li> </ul>

	Forecast for Fiscal 2021	Fiscal 2020 Results
<b>2nd Quarter</b>	¥ 15.00 (including a special dividend of ¥5.00)	¥ 10.00
<b>Fiscal Year-end</b>	¥ 15.00 (including a special dividend of ¥5.00)	¥ 14.00 (including a commemorative dividend of ¥4.00)
<b>Annual Total Dividend</b>	¥ 30.00 (including a special dividend of ¥10.00)	¥ 24.00 (including a commemorative dividend of ¥4.00)
<b>Dividend Payout Ratio</b>	46.3%	31.8%

With regard to the dividend forecast for fiscal 2021, Seikagaku intends to pay an annual dividend of ¥30 per share, representing a dividend payout ratio of 46.3%, to consist of an ordinary dividend of ¥20 (including an interim dividend of ¥10) and a special dividend of ¥10 to commemorate the launch of JOYCLU (including an interim dividend of ¥5).

We have formulated a mid-term management plan with the aim of strengthening the foundation for re-establishing a growth path in response to the rapidly changing business environment.

We will work on priority measures with innovative thinking without being bound by existing frameworks.

**Corporate Slogan of the Mid-term Management Plan**

**INNOVATIVE THINKING**

Creating value based on innovative thinking



**[Our Three Important Measures]**

1. Accelerating new drug discovery to become the pillar of new profits
2. Solidifying the profit foundation through market expansion of new products
3. Productivity improvement reforms

A period to solidify our foundation in order to lay out a path for revived growth



## OUR THREE IMPORTANT MEASURES

# A Period to Solidify Our Foundation in Order to Lay Out a Path for Revived Growth

We will work on three important measures for sustainable growth.

### 1. Accelerating new drug discovery to become the pillar of new profits

#### Strengthening and making use of the Company's own core technology related to GAGs\*

Leveraging drug discovery technology held by Seikagaku to the fullest extent and raise the possibilities for innovative drug discovery.

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

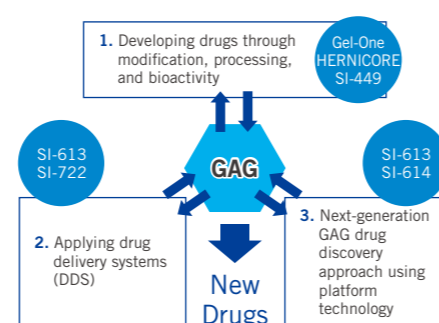
#### Accelerating innovative drug discovery using an Open Innovation strategy

In addition to the technologies in its possession, Seikagaku will proactively undertake initiatives toward technology having high affinity with other companies, maximize synergies, and expand the number of projects in new drug development—all to speed up its work.

#### Steady expansion of the development pipeline with an eye toward global expansion

Seikagaku will quickly foster the development of SI-613, a treatment for osteoarthritis and enthesopathy, as a new core product by applying for and successfully obtaining drug approval, and by achieving launching. Seikagaku also aims to step up clinical studies for SI-722, a treatment for interstitial cystitis and bladder pain syndrome, and SI-449, an adhesion barrier. With regard to SI-6603, an indication for treatment for lumbar disc herniation, the Company will focus on speeding up additional study for the Phase III clinical study as it pursues a full effort toward a U.S. market launching.

Main technologies held by Seikagaku



### 2. Solidifying the profit foundation through market expansion of new products

#### Post-marketing drug development of HERNICORE in Japan

Seikagaku places priority on information provision activities to ensure appropriate use and safety as well as the collection of aftermarket safety information. Upon agreement with the authorities while coordinating with relevant scientific societies, the Company will work toward gradual expansion of requirements for available medical practitioners and facilities together with steady market penetration. The Company will also advance the disease awareness activities related to lumbar disc herniation for patients.



HERNICORE®, a treatment for lumbar disc herniation

#### Accelerating multinational expansion of existing products and products in development

By expediting the cultivation of new markets for existing products and products in development to maximize product value, Seikagaku seeks to solidify its medium- to long-term profit foundation. It will also be actively engaged in product improvement and application development in accordance with medical treatment needs in the targeted expansion regions.

#### Global expansion of endotoxin-detecting reagents that utilize genetic recombination technology

Overseas development of the Seikagaku Group's LAL business is under its U.S.-based subsidiary, the Associates of Cape Cod, Inc. (ACC). With expectations of future adoption, ACC aims for global expansion of gene-recombinant endotoxin-detecting reagents, leading to the securing of a new profit foundation.

### 3. Productivity improvement reforms

#### Thorough cost reductions

In manufacturing costs, as a result of a project that is already underway, Seikagaku will conduct a review of procurement costs and the optimization and streamlining of production, leading to greater assurance of product profitability. In selling, general and administrative expenses, the Company will improve work efficiency and make sure that thorough cost reductions are actually done. Furthermore, in order to carry out new drug development continuously, it will address efficient use of R&D expenses determined by priority.

#### Diversifying the profit model

Regardless of the business model up to now, the Company will carry out a vigorous examination of ways in which to produce new profit.

#### Creating an organization for maximizing the value of resources

Seikagaku will advance organizational reform that enables flexible responses to changes in the business environment and the nurturing of talent that can create new value, and which also lets each person demonstrate their potential to the fullest.



Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020.

## Numerical Targets

	2019/3 results	2022/3 targets
Net sales	¥28.3 billion	¥28.3 billion
Ordinary income	¥2.8 billion	¥4.5 billion
SKK EBITDA*	¥4.6 billion	¥5.0 billion
Overseas sales ratio	42.2%	50.0%

#### <Assumptions>

- Expansion of overseas sales in the LAL business makes up for the effects of the NHI drug price revisions in Japan
- Depreciation expense declines as a result of impairment accounting
- R&D expenses are 25–30% of sales
- Various royalty income is included as non-operating income
- Exchange rate: ¥105 to the U.S. dollar

\*SKK EBITDA:

A profit indicator consisting of operating income plus depreciation expense and royalty income

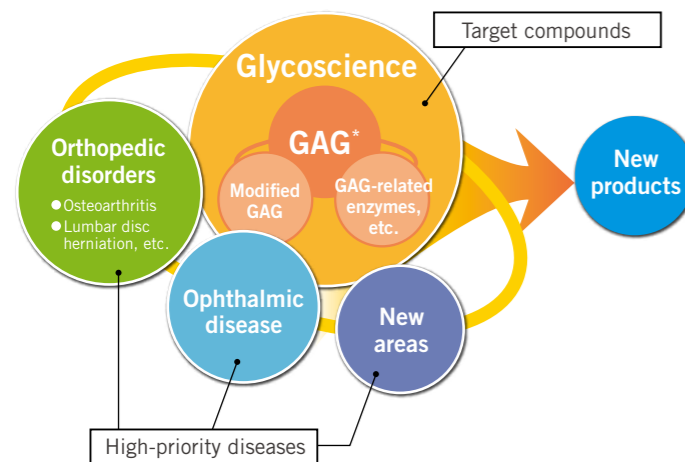


Seikagaku engages in research and development of innovative drugs in the our specialty field of glycoscience. And we contribute to the health and well-being of people around the world.

## 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 combining Seikagaku's DDS technologies with drugs and technologies that other companies possess, not only low-molecular compounds, but also proteins and middle molecules such as peptides and nucleic acids.

## Seikagaku and glycoscience

Seikagaku's Management Creed states: "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 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 in 1987 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.

## Topics

### The TATENO Forum contributes to enhancement of R&D capabilities

Each year in December, the Central Research Laboratory holds the TATENO Forum, an internal presentation forum for sharing research results relating to new ideas and technology creation. In addition to young and mid-career researchers, employees from other business sites participated, discussing the future potential and contribution to medical needs of each research theme.

In consideration of COVID-19, the forum for fiscal 2020 was held online for the first time, with 22 entries presented over a three-day period. At one point there were over 140 attendees, and by utilizing the advantages of holding it online, a lively discussion was had, with presenters answering questions from attendees via the chat function. Through the introduction of telework due to the effects of the COVID pandemic, many of the presented subjects showed ideas and approaches from new perspectives and points of attention.

We will continue to explore appropriate methods of holding future conferences as needed. By deepening interaction among employees through the exchange of ideas and information sharing as well as by contributing to the enhancement of Seikagaku's R&D and technological capabilities, the Central Research Laboratory aims to originate and create development themes, such as new pharmaceuticals that people truly need.



First online TATENO Forum

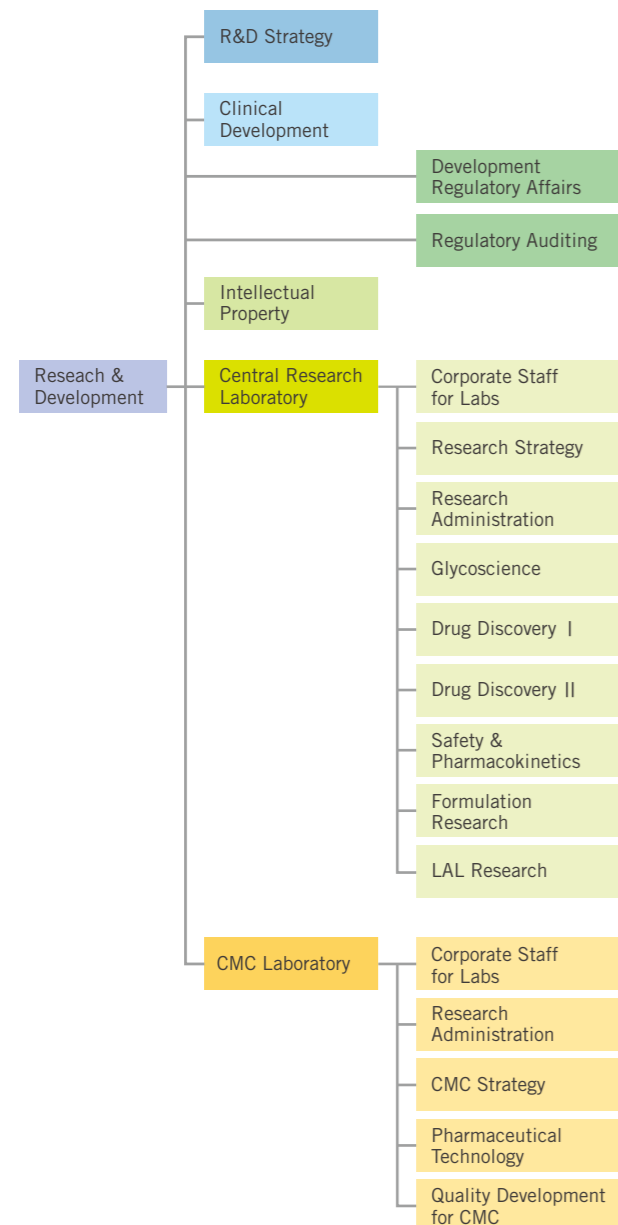
\*The forum name was taken from the location of the Central Research Laboratory (Tateno, Higashiyamato City, Tokyo).

## 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 April 1, 2021)



## 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
- Formulation Research: Exploratory research for the ascertaining and formulation of the physicochemical properties of GAG and GAG-related substances
- 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

## 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 Business Development & Marketing Division, Production Division, and other relevant Company organizations.

## 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.

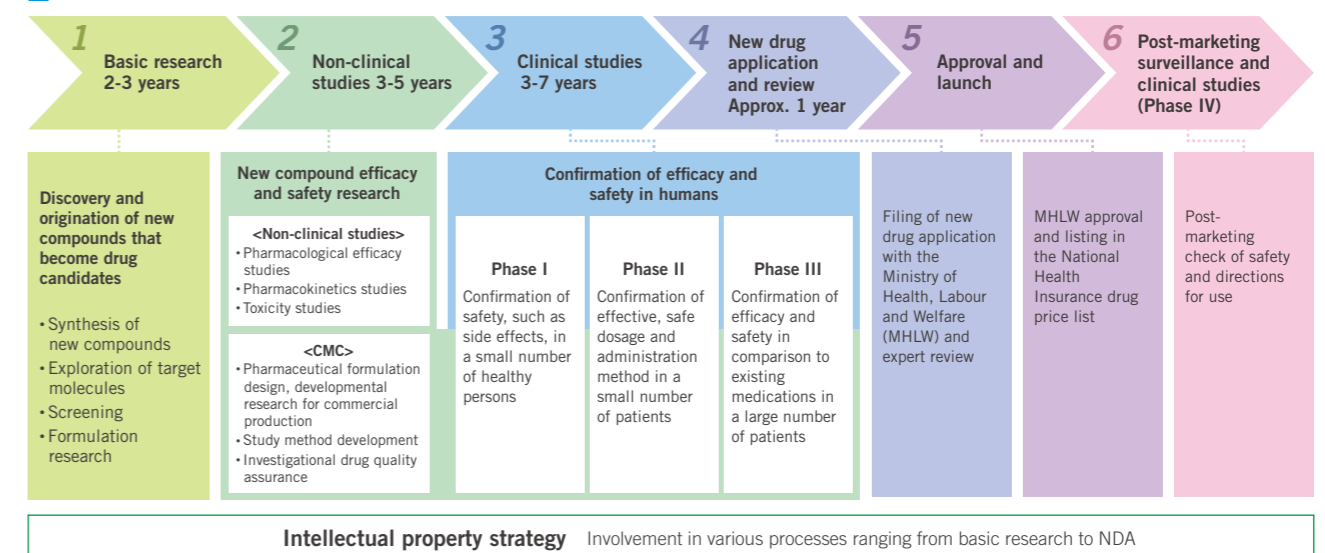
Ordinarily, more than ten years is required from discovery of a candidate substance until its approval as a new drug. Within the long, difficult new drug development process, clinical development is considered to hold the key to whether an NDA can be filed.

## Clinical development

Seikagaku conducts various clinical studies in Japan and the U.S. in cooperation and collaboration with medical experts, medical institutions, and external contract research organizations (CROs) and site management organizations (SMOs). The Clinical Development Department is responsible for creating the integrated development plan (protocols); monitoring of clinical studies; planning and execution of enrollment acceleration; and data management and analysis of study results. It also communicates with the regulatory authorities in various countries and develops dossiers necessary at the time of NDA filing.

In developing protocols, the Clinical Development Department closely communicates with medical monitors and regulatory authorities, identifies requirements for NDA approval and finalizes the study design. In monitoring of clinical studies, the Department works through medical institutions to ensure the quality of studies by confirming whether they are being conducted in conformance with Good Clinical Practice (GCP) and regulatory requirements by ascertaining the condition of subjects and reviewing study data.

## The Drug Research and Development Process



**Ethical considerations concerning research using human biological materials**

Progress in biological science has been accelerating in recent years, together with accompanying innovation of medical technologies. In particular, experiments and research using human biological materials, including genetic information, are yielding new knowledge that is expected to lead to the development of novel, highly beneficial pharmaceuticals.

In keeping with the intent of the Japanese government's guidelines on handling of human materials\*, Seikagaku has established the Code of Ethics for Research Using Human Specimens to make it possible to conduct comprehensive reviews, including evaluation of ethical and scientific validity, when experiments and research using human materials are conducted. To carry out the intent of the Code of Ethics, we have established the Ethical Review Committee for Research Using Human Specimens and publish a list of committee members and minutes of committee meetings through the Japan Agency for Medical Research and Development's Ethical Review Committee Reporting System of the Ministry of Health, Labour and Welfare.

\*Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Only Japanese text available)

**Ethical considerations in non-clinical studies**

In the development of pharmaceuticals and medical devices, research activities using laboratory animals are indispensable to confirm the efficacy and safety of candidate substances, and deeply contribute to the progress and advancement of medical science.

Seikagaku strives to rigorously address ethical considerations in animal experiments and has formulated internal regulations that comply with the Act on Welfare and Management of Animals and Basic Guidelines for Animal Experimentation at Institutes under the Jurisdiction of the Ministry of Health, Labour and Welfare. Also, an ethics committee established within Seikagaku evaluates whether all animal experiments, including outsourced experiments, are planned and conducted in accordance with the 3Rs Principle\*. These initiatives at Seikagaku have been evaluated as conformant by the Japan Pharmaceutical Information Center, a third-party organization.

\*3Rs Principle: Methods that avoid or replace the use of animals (Replacement), methods that minimize the number of animals used per experiment (Reduction), and methods that minimize animal suffering (Refinement)

**Development Pipeline**

**[Pharmaceuticals]**

(As of September 30, 2021)

Development code, substance name	Indication	Developed in	Phase I	Phase II	Phase III	NDA
SI-6603 Condoliase	Lumbar disc herniation	USA			█	
SI-613 Hyaluronic Acid-Diclofenac Conjugates	Knee osteoarthritis	USA		█		
SI-613-ETP Hyaluronic Acid-Diclofenac Conjugates	Enthesopathy	Japan		█ Late-stage Phase II		
SI-614 Modified Hyaluronate	Dry eye	USA			█ Phase II/III	
SI-722 Steroid conjugated with chondroitin sulfate	Interstitial cystitis and bladder pain syndrome	USA	█ Phase I/II			

**[Medical Devices]**

Development code, substance name	Description	Developed in	Pilot study	Pivotal study	NDA
SI-449 Cross-linked Chondroitin Sulfate	Adhesion barrier	Japan		█	

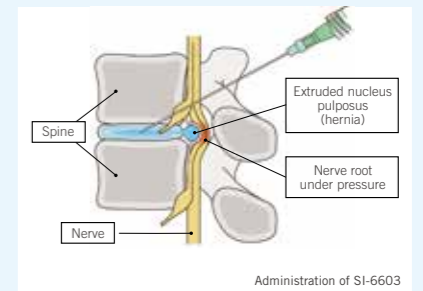
**Overview of Development Pipeline**

**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.

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., although the expected pharmacological effect was demonstrated in a Phase III clinical study, the study did not meet its primary endpoint of improvement in leg pain. In response to this, we began an additional Phase III clinical study in February 2018, with a plan to complete follow-up observations in November 2022. However, the spread of COVID-19 infection has led to some medical institutions suspending clinical trials or halt hospital visits, which has caused delays in trial schedules. As of the end of March 2021, in addition to the operational status of trial facilities trending toward resuming their activities, promotion of subject enrollment has been successful, with enrollment making steady progress. We continue to seek to minimize delays, while also devising measures to reduce COVID-19 infection risk.



**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.

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.

In the U.S., a Phase II clinical study targeting osteoarthritis has been completed, and we are considering a Phase III study while proceeding with selection of a sales partner.

In April 2020, Seikagaku entered into an agreement with Eisai Co., Ltd. concerning co-development of SI-613 and a marketing alliance in China, and in September 2020, an agreement was made with that same company for a marketing alliance in South Korea.

Data analysis of a late-stage Phase II clinical study in Japan of SI-613-ETP for the treatment of enthesopathy has been completed, and we are considering the next clinical study together with co-development and marketing partner Ono Pharmaceutical Co., Ltd.



**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 protecting the ocular surface and promoting corneal wound healing.

In the U.S., a Phase II/III clinical study has been completed, and we are considering a Phase III study while proceeding with selection of a sales partner.



**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.

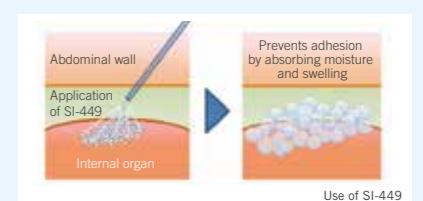
While a Phase I/II clinical trial in the U.S. experienced delays in the trial schedule due to the spread of COVID-19, subject enrollment was completed in January 2021, and tolerability in the patients of this trial has been confirmed. Currently, we are exploring the next phase of trials based on the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

A pivotal study to confirm effect, safety, and operability was initiated in May 2020, but the trial schedule has experienced delays due to the spread of COVID-19 infections. We are currently exploring measures to make up these delays, such as expanding trial facilities, and are working remotely with facilities that have restricted visits.



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 (GMP) 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 are working to improve production efficiency through rigorous regular checks, elimination of human error, and improvement of manufacturing processes. We will continue to pursue continuous improvement and focus on the manufacture and supply of high-quality products that comply with global standards.

## Ensuring a stable supply of products

Providing a stable supply of products is an important mission of a pharmaceutical company. Seikagaku prepares against major disasters and other risks by diversifying raw materials suppliers and maintaining appropriate inventory levels. At the Takahagi Plant, which is responsible for manufacturing the finished products, we have introduced a quake-absorbing structure that reduces shaking for the main production buildings when an earthquake occurs. Through these measures, we have put in place a system capable of stable, reliable product production even in an emergency.

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

## Environmental impact reduction initiatives

Seikagaku is keenly aware of the importance of protecting the global environment. We observe environment-related laws and regulations and voluntarily engage in environmentally friendly business activities. At our plants, in the treatment of water used in pharmaceutical production, we have introduced electro-deionization facilities that use no hydrochloric acid or caustic soda and, in wastewater treatment, we have adopted a system that uses ozone treatment and the activated sludge process.

Also, with the objective of reducing CO<sub>2</sub> emissions, we have established the Energy Conservation Promotion Committee and are managing energy use, and we are implementing improvement measures as well as providing education and training on energy conservation to achieve reduction targets set at each business site. Furthermore, the committee is putting in place a framework for increasing efficiency at the Group level by coordinating energy use and CO<sub>2</sub> emissions results and reduction measures for each fiscal year, reporting to the Management Committee, and deliberating on related matters. As a result, we have achieved our average energy reduction rate targets for the five years up to fiscal 2020.

## Overview of Production Sites

### Takahagi Plant (Takahagi City, Ibaraki Prefecture)

The Takahagi Plant, located in northern Ibaraki Prefecture, is responsible for manufacturing finished pharmaceuticals and medical devices, including the joint function improvement agents that are Seikagaku's mainstay products. When the plant opened in 1975, it had 28 employees. Since the launch of hyaluronic acid formulations in 1987, it has steadily expanded production scale as a manufacturing plant that specializes in injectable formulations. Today, the Takahagi Plant occupies a site of approximately 86,000 square meters and has five production buildings and some 200 employees.

The Takahagi Plant is one of the world's largest manufacturing sites for hyaluronic acid pre-filled syringe formulations\*, producing more than 25 million units per year for the Japanese and overseas markets. 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, opened in 1947 and is Seikagaku's most experienced plant. The plant has some 100 employees and manufactures high-purity hyaluronic acid and chondroitin sulfate for use mainly 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 some of the manufacturing processes for condoliase, the active pharmaceutical ingredient of HERNICORE, a treatment for lumbar disc herniation. The plant is currently preparing to start up new bulk condoliase manufacturing facilities to further strengthen the production scale.

Information on U.S.-based Associates of Cape Cod, Inc. and Canada based Dalton Chemical Laboratories, Inc. is provided in the section "Overseas Subsidiaries" on page 50.



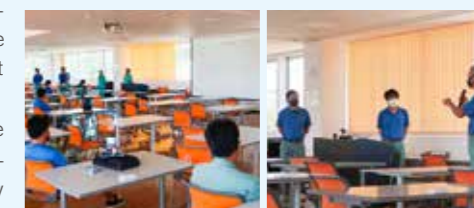
## Topics

### A robust and flexible organization: instilling a Quality Culture

Seikagaku's manufacturing department works to instill in the Company a Quality Culture, so it can be agile and flexible, maximally effective, and capable of reliably manufacturing high-quality pharmaceuticals.

As part of that, we have incorporated the Theory of Constraint (TOC), a philosophy of overall optimization, to develop our human resources to think and act autonomously. We implement a practical learning method greatly different from conventional training where an employee thinks of a subject on their own, takes action to present it, discusses it with everyone, and then considers the next steps.

By adding human resources that can think and act according to the foundation of improvement we have built so far, we encourage participation in activities that work to build an organization that continuously demonstrates high-quality workplace capabilities.



Practical learning for thought and action

Seikagaku has a unique 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

Seikagaku manufactures pharmaceuticals and medical devices with, as their main ingredient, glycosaminoglycans (GAG) such as hyaluronic acid, which are the structural components of glycoconjugates, and also products based on enzymes that act on GAG. To deliver these products to patients globally, Seikagaku forms partnerships with pharmaceutical companies that have expertise in each market, including Japan.

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

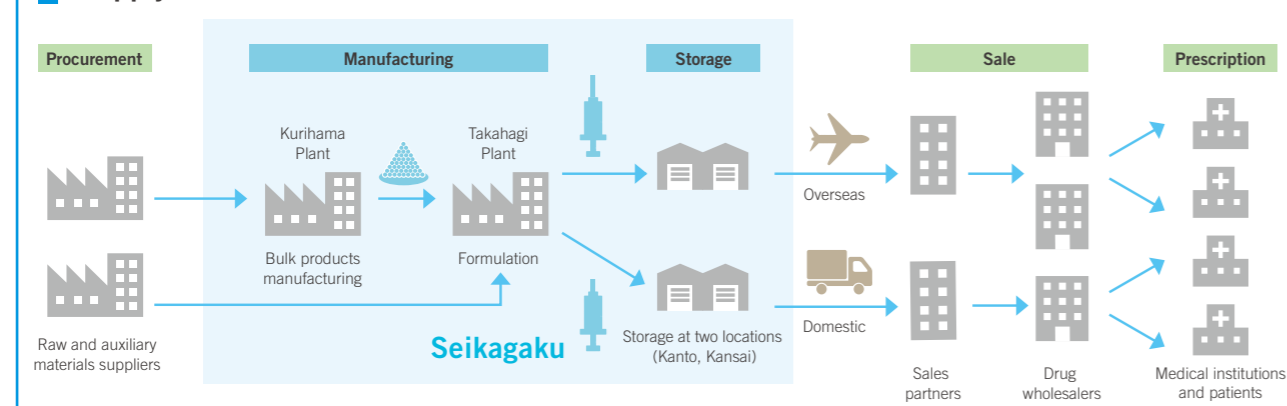
Using proprietary extraction and purification technologies, Seikagaku manufactures high-purity and high-quality hyaluronic acid and chondroitin sulfate and sells them to pharmaceutical and cosmetic companies, and others globally.

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.

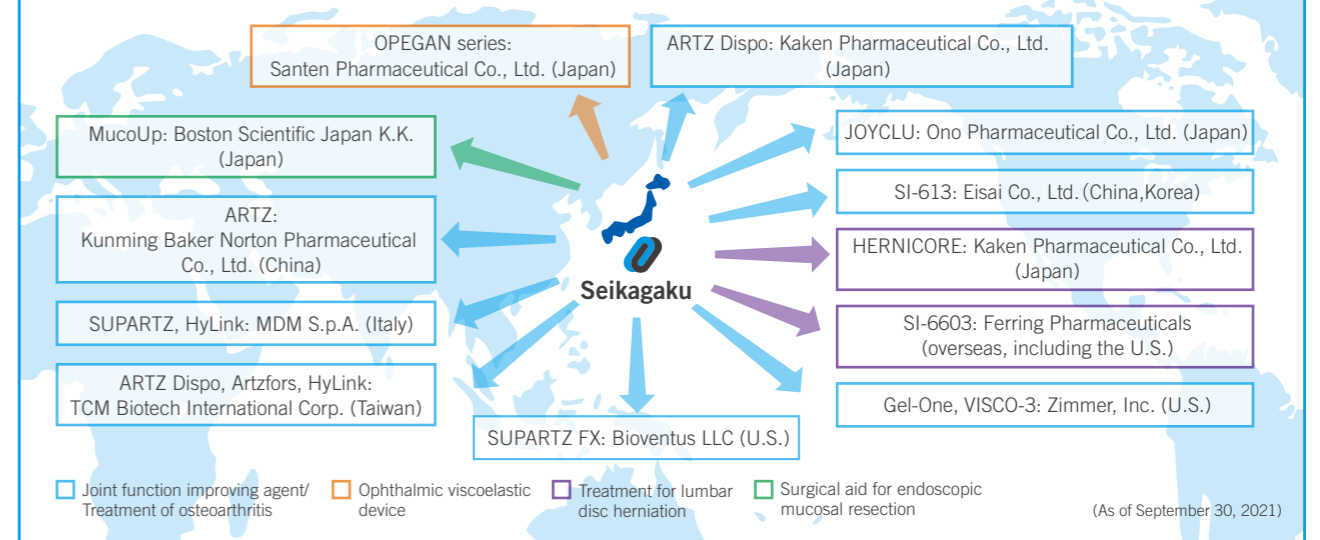
Contract development and manufacturing organization (CDMO)

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 manufactur-

Supply Chain for Main Products



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



ing, 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.

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 amoebocyte lysate (LAL), and it obtained U.S. Food and Drug Administration (FDA) 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.

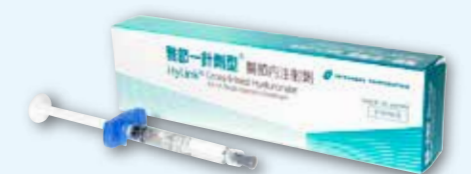
Topics

Launch of HyLink intra-articular single-injection joint function improving agent in Taiwan.

In August of 2021, Seikagaku began sales of HyLink in Taiwan.

HyLink is an intra-articular single-injection viscosupplement (a medical device for the treatment of knee osteoarthritis). Its main ingredient is a hyaluronate hydrogel created using Seikagaku's unique cross-linking technology. Since the highly viscoelastic hyaluronate hydrogel remains in the knee joint cavity for a long period of time, even administering only 3mL can be expected to provide a long-lasting improvement of symptoms.

Since the population is aging, the Taiwanese market for hyaluronic acid treatments is expected to grow. With the addition of HyLink to the multiple-injection joint function improving agents (ARTZ Dispo and Artzfors) that are already on the market, patients will be provided even more treatment options, contributing to improvements in their quality of life.



HyLink®



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 makes maximum effort to ensure quality at every stage, from R&D to post-marketing, by complying with the pharmaceutical laws and regulations of overseas countries, including a collection of regulations and guidelines called GxP\*. In Japan, as a marketing authorization holder, we have developed a system with three key roles (general marketing compliance officer, quality assurance supervisor, and safety management supervisor) and implement appropriate quality management and pharmacovigilance operations in accordance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act").

To continue to reliably provide pharmaceuticals and medical devices required by patients around the world, we will strive to maintain and enhance quality assurance and compliance systems in accordance with global standards.

\*GxP is an abbreviation for Good XXX Practice, a collective term for standards established to ensure the efficacy, safety, and quality of pharmaceuticals and medical devices from the R&D stage to post-marketing. (See the diagram to the right.)

## 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 peri-arthritis of the shoulder. We strictly maintain and control quality at all stages from product design and development to

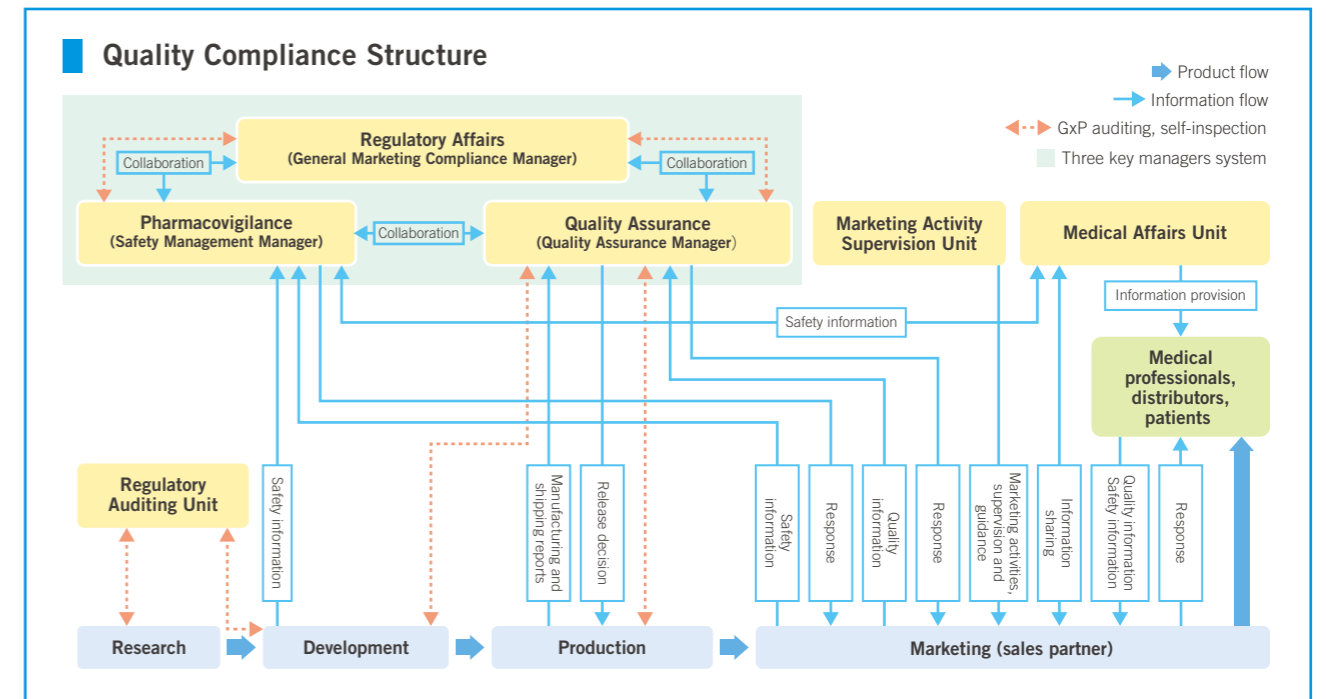
post-marketing in conformance with these manufacturing control and quality assurance systems.

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.

## Laws and Regulations Governing Pharmaceuticals and Medical Devices

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

- PMD (Pharmaceutical and Medical Device) 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 manufacturing
- 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



## 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.

## Medical information collection and provision activities

Seikagaku has established the Medical Affairs Unit, which engages in activities to provide current scientific knowledge to external professionals independently from the marketing division. As scientific experts with sufficient ethical perspective, the unit contributes to medical progress by creating and disseminating medical evidence relating to disease information and products in the fields in which Seikagaku focuses, such as orthopedic disorders and ophthalmic diseases.

## Topics

### Measures to strengthen data integrity by cooperating with quality assurance departments

To provide a stable supply of high-quality pharmaceuticals and medical devices, the Quality Assurance Department engages in activities to develop and maintain a quality management system based on our Quality Policy.

These days, ensuring data integrity is important not only in operation of the quality management system for existing products, but also in the pursuit of new drug development and overseas business development. The department supports quality operations company-wide through operation of a quality operations management system as well as use of a document management system for handling documents and records in accordance with GxP standards.

To strengthen data integrity, the Quality Assurance Department cooperates with quality assurance departments, including those at the plants and laboratories, in utilizing systems and executing quality operations to ensure continuous quality assurance.



A Quality Assurance Department staff meeting to support quality operations

Seikagaku aims to develop self-driven and self-disciplined employees who can create new value and contribute to sustainable corporate growth.



## Development of human resources

Seikagaku Corporation considers human resources to be an important corporate asset and seeks people who understand and put into practice our core values “creativity,” “fairness,” and “dreams and passion” and are capable of self-growth while fulfilling their roles with a sense of responsibility.

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. In response to the spread of COVID-19, we continue to switch from group training to online training.

## 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. In the fiscal year ended March 31, 2021 (fiscal 2020), we instituted a work-from-home system as an option for diversifying work styles. Other objectives for introducing this system were to increase productivity through greater operational efficiency and create a means of maintaining continuity of operations in the event of a disaster.

Employees used an average of 70.2% of paid leave in fiscal 2020. From fiscal 2007 to fiscal 2020, 100% of staff

who left work for childcare reasons returned, and the number of male employees taking childcare leave has also increased. Furthermore, Seikagaku creates employee-friendly workplaces through staff assignments that correspond to the nature and amount of work, improvement of workplace environments, and by limiting long working hours.

## Diversity management

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

In 2016, we launched a project to promote women’s advancement in the workplace and raise awareness within the company. Since then, we have engaged in activities to improve internal systems based on comments made in interviews with all female employees. As of March 31, 2021, the ratio of female managers was 16.9%, a sharp increase from 7.9% four years earlier.

In fiscal 2019, we changed the project into a diversity and inclusion project. To ensure that the contributions and successes of diverse employees are the driver of Seikagaku’s sustained growth, we have set concrete targets for each business site and are proceeding with reforms to create an organization in which individuals can demonstrate their full potential.

## Mental healthcare

Since 2009, Seikagaku has implemented measures aimed at maintaining the physical and mental health of employ-

ees 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.

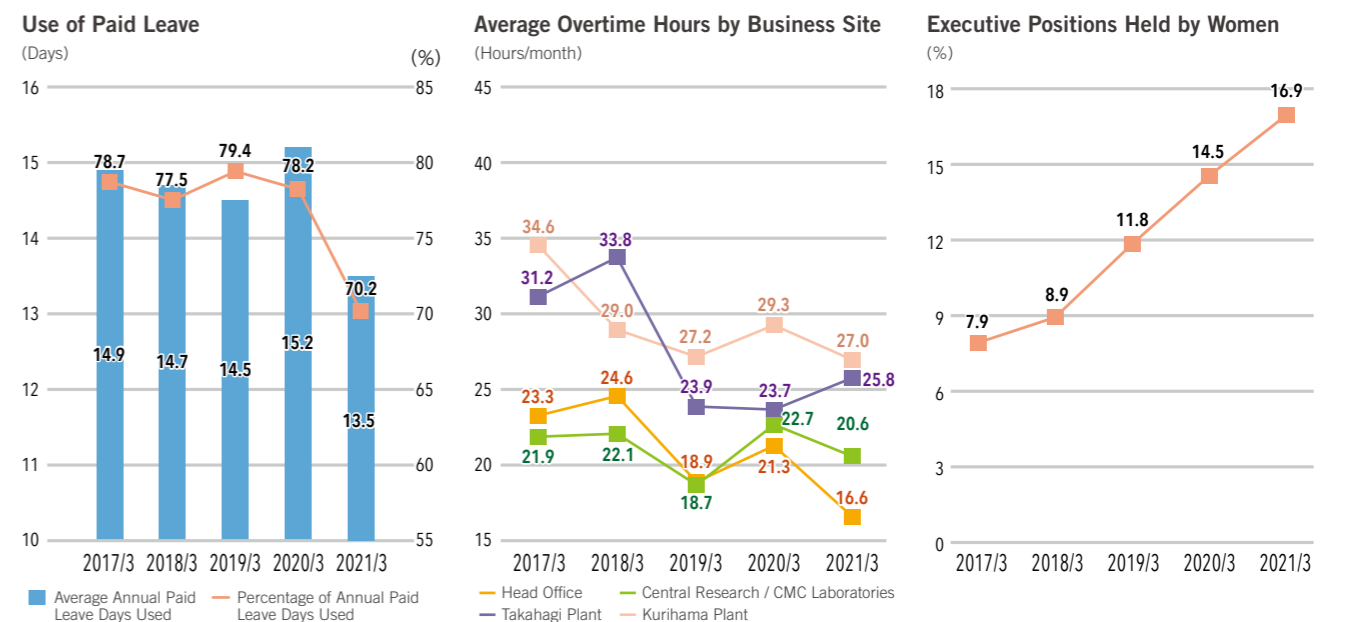
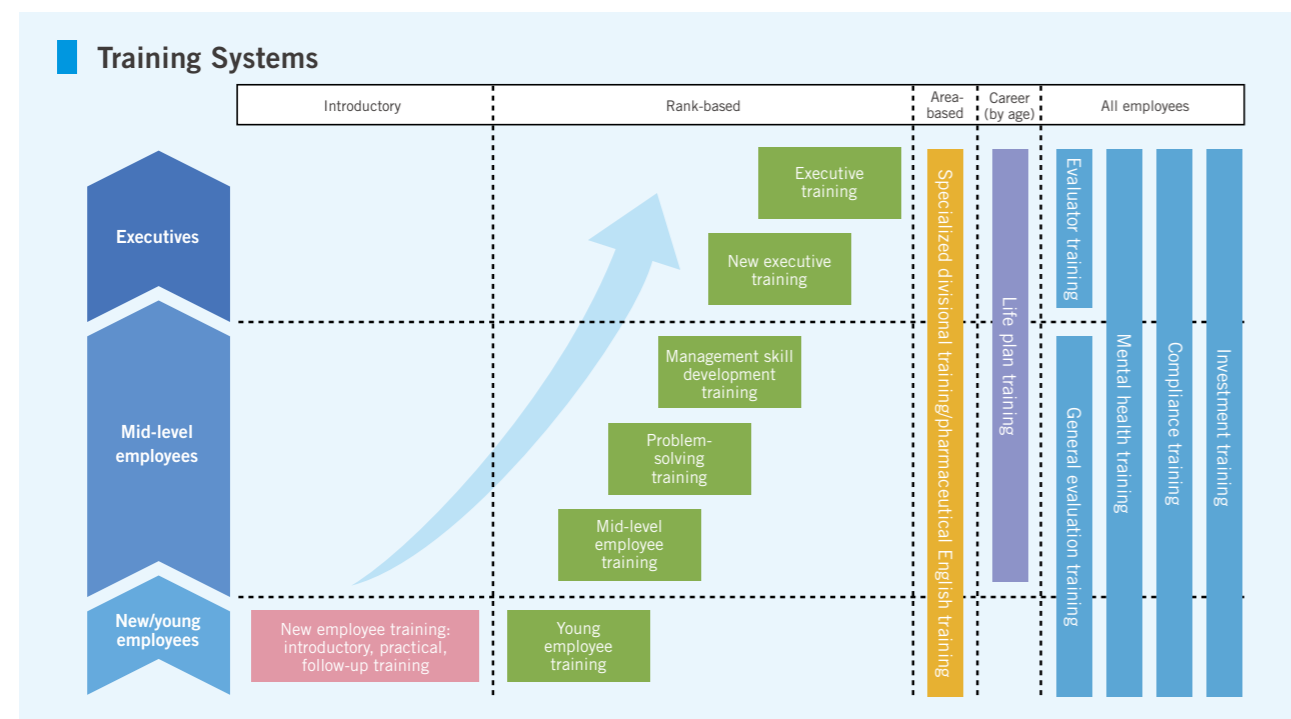
## COVID-19 infections countermeasures

Seikagaku is implementing infection prevention measures that give the highest priority to our business partners, employees and their families, and local residents. We prudently review this arrangement in accordance with the current infection situation and other considerations and strive to raise employee awareness by circulating information internally about key points and rules concerning infection prevention.

As a rule, in workplaces where working from home is a practical solution, we instruct employees to do so. We are changing commuting methods and expanding operation of a flextime system to prevent COVID-19 infections while also realizing flexible work styles for employees.

From July to September 2021, we strove to prevent the spread of infection by providing workplace COVID-19 vaccinations for about 600 employees and their family members and employees of business partners who wished to be vaccinated.

\*Information in this section is current as of September 30, 2021.



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



## Members of the Board (as of October 1, 2021)

### Directors



President & CEO  
**Ken Mizutani**  
 Term of office as Director: 31 years  
 Number of the Company's shares owned: 456,003 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  
 Business Development & Marketing  
**Toshiyuki Okada**  
 Term of office as Director: 4 years  
 Number of the Company's shares owned: 9,758 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 (current position)



Executive Vice President  
 Research & Development  
**Yosuke Funakoshi**  
 Term of office as Director: 3 years  
 Number of the Company's shares owned: 10,358 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)

### Audit & Supervisory Board Members



Audit & Supervisory Board Member  
**Toru Takeda**  
 Term of office as Audit & Supervisory Board Member: 5 years  
 Number of the Company's shares owned: 2,200 shares

- Apr. 1983 Joined The Long-Term Credit Bank of Japan, Limited (current Shinsei Bank, Limited)
- Oct. 2000 Joined The Industrial Bank of Japan, Limited (current Mizuho Bank, Ltd.)
- Oct. 2008 General Manager, Risk Management Department, Mizuho Trust & Banking Co., Ltd.
- Apr. 2012 Corporate Auditor (full-time)
- Apr. 2016 Joined the Company as Senior Vice President
- June 2016 Audit & Supervisory Board Member (current position)



Audit & Supervisory Board Member  
**Shigeru Kawahara**  
 Term of office as Audit & Supervisory Board Member: 4 years  
 Number of the Company's shares owned: 5,300 shares

- Apr. 1982 Joined Nippon Merck Banyu Co., Ltd. (current MSD K.K.)
- May 2008 Joined the Company
- June 2009 General Manager of Marketing Planning Department
- Sept. 2010 General Manager of International Marketing Department and Marketing Planning Department
- Jan. 2014 General Manager of Audit Department
- June 2017 Audit & Supervisory Board Member (current position)



Outside Audit & Supervisory Board Member  
**Mie Fujimoto**  
 Term of office as Audit & Supervisory Board Member: 6 years  
 Number of the Company's shares owned: 1,400 shares

- Apr. 1993 Admitted to the bar in Japan
- Apr. 1993 Joined New Tokyo International (Later, Bingham Sakai Mimura Aizawa (foreign law joint enterprise))
- Apr. 2015 Joined TMI Associates (current position)
- June 2015 Outside Audit & Supervisory Board Member of the Company (current position)



Executive Vice President  
 Corporate Strategy, HR, F&A and Corporate Staff and Head of Corporate Strategy  
**Takayuki Akita**  
 Term of office as Director: 3 years  
 Number of the Company's shares owned: 6,958 shares

- Apr. 1986 Joined The Mitsubishi Bank, Limited (current MUFG Bank, Ltd.)
- May 2016 Executive Vice President, Head of Transaction Banking
- June 2017 Joined the Company as Advisor
- June 2017 Executive Vice President responsible for Corporate Planning
- Oct. 2017 Executive Vice President and Head of Corporate Strategy
- June 2018 Member of the Board, Executive Vice President responsible for Corporate Strategy, HR, F&A and Corporate Staff and Head of Corporate Strategy (current position)



Outside Member of the Board  
**Mio Minaki**  
 Term of office as Director: 2 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** (New election)  
 Term of office as Director: —  
 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)



Outside Audit & Supervisory Board Member  
**Shinkichi Matsuo**  
 Term of office as Audit & Supervisory Board Member: 2 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: 1 year  
 Number of the Company's shares owned: —

- Apr. 2000 Admitted to the bar in Japan
- Apr. 2000 Joined Nagashima Ohno & Tsunematsu
- Sept. 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)

### Executive Vice Presidents

Quality Compliance & Medical Affair  
 Executive Vice President  
**Yuji Shimojima**

Head of Corporate Staff  
 Executive Vice President  
**Mikako Torii**

Head of Takahagi Plant  
 Head of Production  
 Executive Vice President  
**Masayuki Ito**

- Notes:
1. Ken Mizutani concurrently serves as Executive Vice President.
  2. Terms of office are as of June 22, 2021.
  3. Number of the Company's shares owned is as of March 31, 2021.

## Basic policy of corporate governance

Seikagaku Corporation views corporate governance as a core area of management priority, and endeavors to gather information accurately and adequately, speed up decision-making, and strengthen the supervisory function of business execution. We are profoundly aware of our social mission and responsibilities as a pharmaceutical company, and are committed to always earning the confidence of stakeholders, including our shareholders. In addition to establishing internal control systems, such as for compliance and risk management, we are enhancing our corporate governance through mutual collaboration among departments within the Company in order to create a management environment that meets the expectations of society.

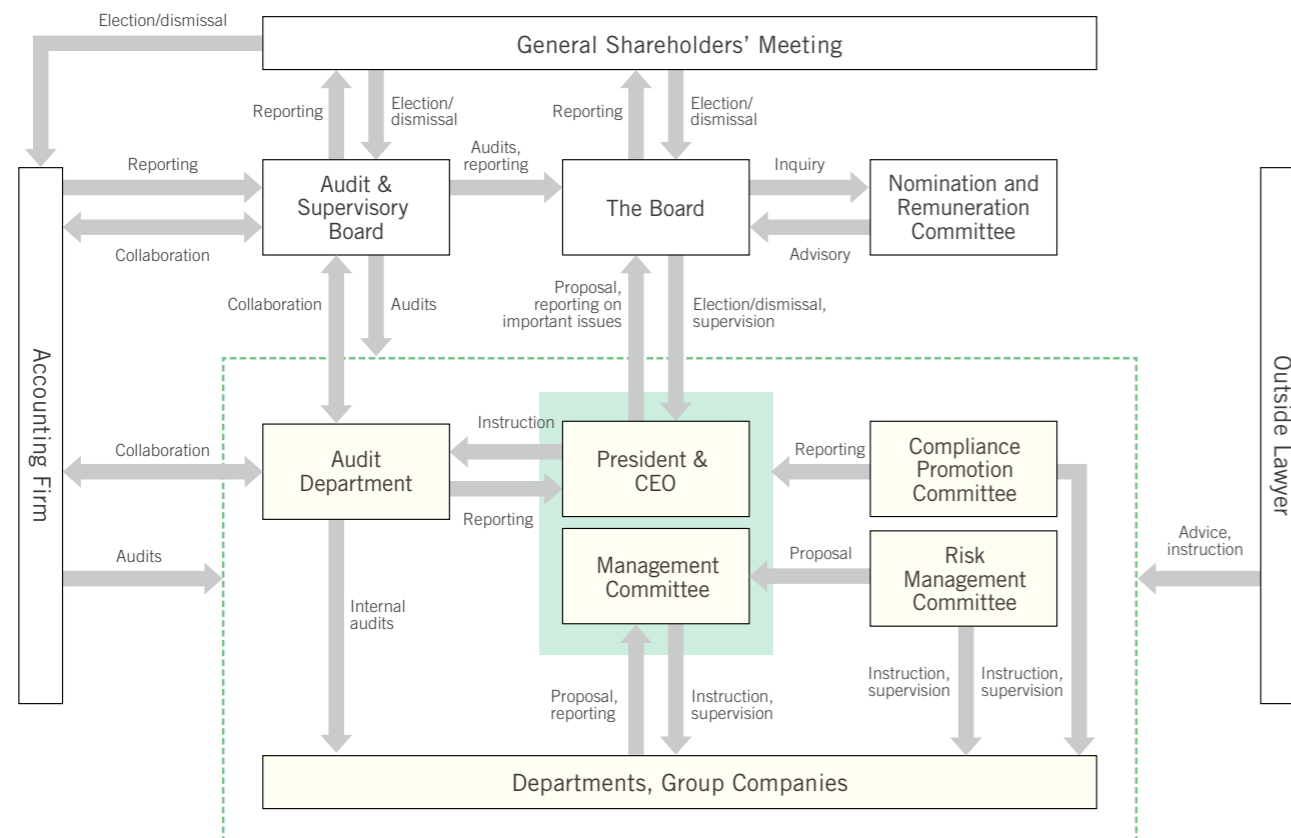
## Corporate governance structure

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 holds weekly Management Committee meetings to confer and decide important management agendas, based on the basic policy of the Board of Directors.

The Board of Directors has established the Nomination and Remuneration Committee, which consists of the president & CEO and all outside members of the Board, to advise on matters concerning nomination of candidates for members of the Board and compensation.

The Compliance Committee promotes various programs to improve compliance effectiveness, and the Risk Management Committee appropriately manages business risks and implements risk prevention measures.

## Corporate Governance Structure



## Board of Directors

The Board of Directors comprises six 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 of the Board seats.

The Board makes decisions on tasks stipulated in laws, the Articles of Incorporation, and rules for the Board, such as basic management policy, the mid-term management plan, the annual management plan, and election of executive vice presidents. The Board decides on important business and supervises the performance of business operations and oversees business execution. The Board holds regular monthly meetings and, if necessary, additional meetings of the Board are convened.

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 all the outside members of the Board and outside Audit & Supervisory Board members, periodically analyzes and evaluates the effectiveness of the Board of Directors. The Board deliberates the evaluation results and undertakes improvement of Board operation.

All two 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. The Board selects candidates for corporate officer positions taking into consideration their knowledge, experience, abilities, and character, in addition to specific skills and Board diversity, to maintain a structure capable of effectively fulfilling the Board's role and duties.

Since the skills required by the Board of Directors constantly change according to the business environment and other factors, the Company plans to periodically review 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.

## 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	Human resources/Labor
President & CEO	Ken Mizutani	●		●	●		●	
Executive Vice President	Toshiyuki Okada	●			●	●	●	
Executive Vice President	Yosuke Funakoshi	●			●	●		
Executive Vice President	Takayuki Akita	●	●	●		●		●
Outside Member of the Board	Mio Minaki			●				●
Outside Member of the Board	Yasuyuki Sugiura	●	●			●		●
Audit & Supervisory Board Member	Toru Takeda		●	●				
Audit & Supervisory Board Member	Shigeru Kawahara				●	●		
Outside Audit & Supervisory Board Member	Mie Fujimoto			●		●		●
Outside Audit & Supervisory Board Member	Shinkichi Matsuo	●	●					
Outside Audit & Supervisory Board Member	Takayuki Maruyama			●		●		

## Audit & Supervisory Board

The Audit & Supervisory Board comprises five members, including three outside members. Its duties include discussing and deciding important audit-related matters and confirming in advance matters for resolution by the Board of Directors.

Audit & Supervisory Board members attend meetings of the Board of Directors and express their opinions as necessary and also interview directors in charge and corporate officers of subsidiaries in accordance with an annual plan, and exchange views with the president & CEO. They also 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 suitably perform supervision of 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 three outside Audit & Supervisory Board members are reported to the Tokyo Stock Exchange, Inc. as independent officers by the Company.

## Nomination and Remuneration Committee

In the interest of increasing fairness, transparency, and objectivity of procedures relating to the nomination and remuneration of members of the Board of Directors, Seikagaku has established the Nomination and Remuneration Committee, comprising the president & CEO and both independent outside members of the Board, as a voluntary advisory body to the Board.

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. The committee also decides the amount of monetary compensation for individual members of the Board and other matters for which decision-making has been delegated by the Board of Directors.

In fiscal 2020, the committee deliberated the selection of candidates for members of the Board and matters relating to determining remuneration for members of the Board as well as the Policy for Determining the Details of Individual Remuneration for Members of the Board and Audit & Supervisory Board Members.

## Status of Holding of Board of Directors and Other Meetings (Fiscal 2020)

Organizational body	Composition	Frequency of convocation	Purpose
The Board*1	Members of the Board: 6 (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 2020.
Audit & Supervisory Board	Audit & Supervisory Board members: 5 (including 3 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 15 times in fiscal 2020.
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 2020.
Management Committee	Members of the Board: 4 Executive vice presidents: 3 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.

\*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 and insight relating to corporate legal affairs developed over many years in the judicial field. 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	Mie Fujimoto	As a lawyer, Ms. Mie Fujimoto is highly knowledgeable in corporate legal affairs, with a focus on labor-related laws and regulations. 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.
	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 is highly knowledgeable in corporate legal affairs, with a focus on 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.

## Main Activities of the Outside Members of the Board (Fiscal 2020)

Category	Name	Main activities
Outside member of the Board	Mio Minaki	Ms. Mio Minaki attended all meetings of the Board of Directors held in fiscal 2020 and offered advice and recommendations on numerous occasions at Board meetings from a professional point of view based on a wealth of experience and professional insight relating to corporate legal affairs. In her capacity as a member of the Nomination and Remuneration Committee, she actively offered advice and recommendations about Board member personnel proposals, the appropriateness of the compensation system for corporate officers, and other matters.
	Yasuyuki Sugiura	Took office on June 22, 2021.
Outside Audit & Supervisory Board member	Mie Fujimoto	Ms. Mie Fujimoto attended all Audit & Supervisory Board meetings held in fiscal 2020 and actively expressed opinions at meetings from an independent, objective point of view based on professional insight, mainly relating to labor-related laws and regulations and corporate compliance. 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 all meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.
	Shinkichi Matsuo	Mr. Shinkichi Matsuo attended all Audit & Supervisory Board meetings held in fiscal 2020 and actively expressed opinions at 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 all 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 attended all Audit & Supervisory Board meetings held after he took office and actively expressed opinions at 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 all meetings of the Board of Directors and offered advice and recommendations on numerous occasions from an expert point of view.

## Initiatives to Strengthen Corporate Governance

(Fiscal year)

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Number of members of the Board	11	9		7					8					5			6		
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							
Number of female Audit & Supervisory Board members																1			
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

## 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)>

Earnings-linked compensation is determined through SKK EBITDA\* in the previous fiscal year. SKK EBITDA is a numerical target in the mid-term management plan (fiscal 2019 to fiscal 2021).

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 and royalty income. The Company has selected SKK EBITDA because it considers it appropriate as a short-term incentive with respect to business performance each fiscal year. The SKK EBITDA target for fiscal 2021, the final year of the current mid-term management plan, is ¥5,000 million. Actual SKK EBITDA for fiscal 2020 was ¥3,057 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 evalua-

tion 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.

## Analysis and evaluation of the effectiveness of the Board of Directors

At Seikagaku, a meeting of outside officers, comprising the outside directors 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 the results of evaluation are discussed by the Board. In this way, Seikagaku seeks to further improve the effectiveness of the Board by periodically identifying issues and continuously engaging in improvement activities.

The evaluation for fiscal 2020 found that the Board of Directors functions properly in deciding important matters and overseeing business execution and that its effectiveness

is sufficiently ensured. It also found that Board meetings are held without delay thanks to the timely introduction of a remote meeting system, notwithstanding the COVID-19 crisis, and that the Board seeks to activate deliberation by promoting advance explanations concerning important agenda items.

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 continued deliberation and discussion of important agenda items and further clarifying Board meeting agenda proposal criteria, and the Board will examine these proposals.

## Total Amount of Compensation for Each Category of Officer, Total Amount by Type of Compensation, and Number of Relevant Officers

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)	203	178	6	6	11	4
Outside members of the Board	25	25	—	—	—	2
Total	228	203	6	6	11	6
Audit & Supervisory Board members (excluding outside officers)	45	45	—	—	—	2
Outside Audit & Supervisory Board members	22	22	—	—	—	4
Total	68	68	—	—	—	6
Grand total	296	271	6	6	11	12

- Notes: 1. Based on the status at the time of adjournment of the 74th Ordinary General Shareholders' Meeting, held on June 19, 2020, one retired outside Audit & Supervisory Board member is 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

The Company takes appropriate measures to ensure that shareholder rights, including voting rights at the General Shareholders' Meeting, are substantially secured. Specifically, to secure sufficient time for consideration in the exercise of voting rights, in a typical year the Company sends out the Notice of Convocation three weeks before the date of the General Shareholders' Meeting and also posts the Notice of Convocation on the corporate website four 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 above-mentioned 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 corporate officer in charge of administration as the person responsible for 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 2020, the Company held 56 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.

### Messages from an outside member of the Board and outside Audit & Supervisory Board member



**Mio Minaki**  
Outside Member of the Board

### Enhancement of corporate value through speedy decision-making and highly effective oversight

I believe that Seikagaku's governance system complies with the revisions that have been made to the Corporate Governance Code in recent years. A discretionary Nomination and Remuneration Committee has been established, and concerning the process for determining compensation for corporate officers, objectivity and transparency have been ensured. Although meetings of the Board of Directors are currently held online due to the impact of COVID-19, if anything, the quality of discussion has actually improved because briefing materials are always distributed before Board meetings, and individual explanations of important matters are provided in advance. I feel

that this, together with a Board that considers age and gender diversity, has created an atmosphere allowing for active discussion that utilizes viewpoints different from the executives responsible for business execution. Informal discussion meetings are held from time to time with the president & CEO and with individuals in charge of divisions and departments, who form the core of those overseeing business execution. These meetings provide opportunities for outside members to personally experience the status of management policies and Seikagaku's corporate culture, which is extremely beneficial when making important decisions.

A key factor that contributes to the corporate value of a pharmaceutical company is continuously providing society with a steady stream of new drugs through R&D. Another important factor that positively affects corporate value is maintaining high corporate ethics to earn the trust and support of society. With this in mind, I recognize that engaging in both speedy decision-making and highly effective oversight are important priorities for the Board. Since rules to increase transparency in the agenda item selection process have recently been developed, I will redouble my efforts to ensure the Board of Directors fully demonstrates its functions and contribute to the enhancement of corporate value.



**Shinkichi Matsuo**  
Outside Audit & Supervisory Board member

### Preparing to realize sustained growth and create medium- and long-term corporate value

Outside Audit & Supervisory Board members are responsible for monitoring corporate management on behalf of shareholders. Although at Seikagaku, various means are employed to provide ample information to the outside members of the Board and outside Audit & Supervisory Board members, I think it is necessary to always dive deeply into the information provided, not merely perform a superficial examination.

Since Seikagaku has adopted a business model that, even among pharmaceutical companies, places a particularly heavy emphasis on R&D, the selection, modification, and discontinuation of new drug development projects constitute extremely important management decisions. I have seen that productive discussion occurs when such decisions are made, with each outside member of the Board and outside Audit & Supervisory Board member asking questions and expressing opinions until they are satisfied, and with members of the Board in charge providing detailed explanations in response.

As someone who has many years of practical experience at an audit corporation and who also has knowledge of finance and accounting, I have paid particularly close attention to matters such as internal controls related to financial reporting, metric-based management, the reasonableness of auditing by the accounting auditor, the management of overseas subsidiaries, and the sufficiency of prior consideration at the time of M&As.

Although pharmaceutical companies face an increasingly adverse business environment, Seikagaku is pursuing sustained growth and medium- to long-term corporate value through the development of innovative new drugs and overseas development. As an outside Audit & Supervisory Board member, I want to deepen my understanding of Seikagaku's business and policies.

## 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.

■ For details on the Compliance Program, please visit the Seikagaku corporate website.

<https://www.seikagaku.co.jp/en/corporate/compliance.html>

## Compliance initiatives

Seikagaku instills compliance by distributing to all employees the Compliance Program Handbook, which sets down compliance standards, procedures, and a promotion framework, and the Compliance Card, which summarizes key points of employee behavior.

**コンプライアンスカード**  
経営陣とコンプライアンス

当社は「独立・公正・健全・透明」の経営理念のもと、独自の医薬品等の開発を通じて世界の人の健康をよりよく支えることに貢献しています。経営陣が率先してコンプライアンス・プログラムは、当社の行動の基となるべきものです。

**私たちの使命**

私たちは、生命関連企業に求められる高い倫理観のもと、コンプライアンス・プログラムおよび法令等を遵守して、顧客かつ公正に行動します。→当社コンプライアンス行動指針より

**生化学工業株式会社**

**行動のポイント**

- 心づくしに「正しいこと」と思わないこと  
法令改正などの環境変化によって「いつものこと」が違反行為に変わることがあります。
- 自分だけが正しいと思うと関わらないこと  
周囲での相談や専門家の知恵を借りることにより、早期解決につながります。
- 疑わしき、迷った「見える」こと  
あなただけ「見える」ことにより、問題の深刻化を防ぐことができます。上司・報告・相談するほか、相談窓口も利用することができます。

**【相談の窓口】**  
（ネットライン）社内・社外  
（コンプライアンス）社内  
※詳細は「相談窓口の手引き」をご覧ください。

Compliance Card

## Compliance education and training

In other measures to promote compliance, Seikagaku provides internal training on specific compliance-related themes every fiscal year to constantly raise compliance awareness. In fiscal 2020, Seikagaku made “Promoting understanding of revisions to relevant laws and regulations and steadily putting into practice the Code of Conduct” an activities policy and engaged in compliance promotion activities centered on online training and e-learning.

### Training Results in Fiscal 2020

Training theme	Details
Workplace harassment training for managers (Sept.)	1) Reconfirmation of basic knowledge of harassment 2) Reflection on one's own language and actions as an employee of an organization 3) Considerations and approaches when providing guidance to subordinates
Traffic safety training (Jan.)	1) Reconfirmation of traffic rules 2) Confirmation of precautions when riding a bicycle
Workplace harassment training for regular employees (Mar.)	1) Acquisition of basic knowledge of harassment 2) Understanding the difference between workplace harassment and legitimate guidance 3) Harassment that tends to occur with remote work 4) Key points for preventing harassment
Code of Conduct training (Mar.)	1) Summary of revisions to the Code of Conduct 2) Test to confirm awareness and understanding

### Diagram of Implementation Structure



\* Overseas subsidiaries Associates of Cape Cod, Inc. and Dalton Chemical Laboratories, Inc. have developed their own compliance frameworks that conform to their local environments, laws, and regulations and have instituted a system of reporting important compliance-related incidents to Seikagaku following reporting to their respective boards of directors.

#### <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.

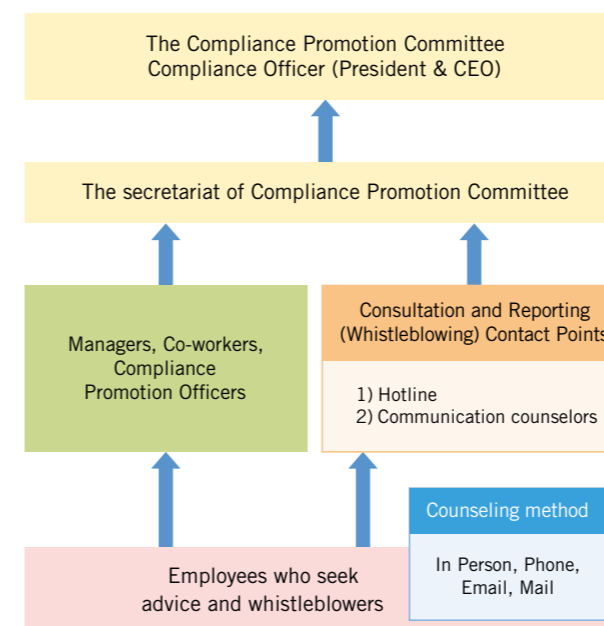
## Consultation and reporting (whistleblowing) contact points

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 instituted hotline operation standards and has also set up a communications counseling system to respond to requests for consultation concerning communications, including harassment. 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.

In fiscal 2020, there were 15 requests for consultation, all of which were handled appropriately.

### 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 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.

## 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.

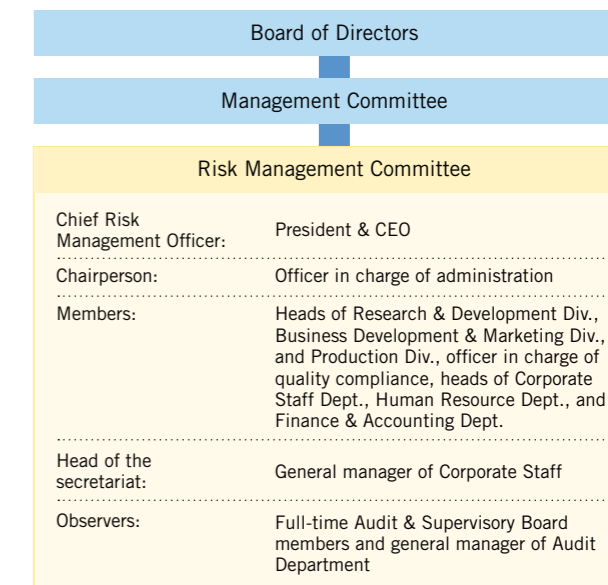
■ Business risks are described on our website.

<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.

### Risk Management Structure



# SOCIAL CONTRIBUTION ACTIVITIES

Seikagaku engages in initiatives to address social and environmental problems in pursuit of harmony and continuous growth together with local communities.

## Promoting communication with the local community by making an athletic field available for use

Since 2007, Seikagaku has contributed to the nurturing of children by providing an athletic field located on the premises of the Central Laboratory and CMC Laboratory for use by Higashiyamato City Daihachi Elementary School, which is located adjacent to the laboratories, for physical education classes and outdoor activities. It is a joy to hear the cheerful voices of children playing and exercising on the field, and we will continue our efforts in building good communication to continue engaging in business activities as a member of the local community with the understanding and cooperation of local residents.



An extracurricular lesson

## Horseshoe crab conservation activities of 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. In addition to supporting the American horseshoe crab, in 2019, ACC began providing assistance for activities to maintain the population of Asian horseshoe crabs in the form of customized aquaculture equipment and training. 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, and is already provided to organizations in China and Malaysia.

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 instruction regarding in vitro fertilization methods and training in the operation of highly efficient aquaculture equipment.

The number of American horseshoe crabs that ACC has released in the Commonwealth of Massachusetts has reached about one million as of July 31, 2021.

In parallel with these conservation activities, ACC has also focused on development of 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 path-

way 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 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.

\* Endotoxin-detecting reagents used in quality control for manufacturing processes of pharmaceuticals and medical devices



Released American horseshoe crabs



PyroSmart NextGen™

Seikagaku pursues 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 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 promptly disseminates science paper information, including commentary from global leading researchers and academic conference information. The site enjoys strong support from researchers in Japan and overseas.



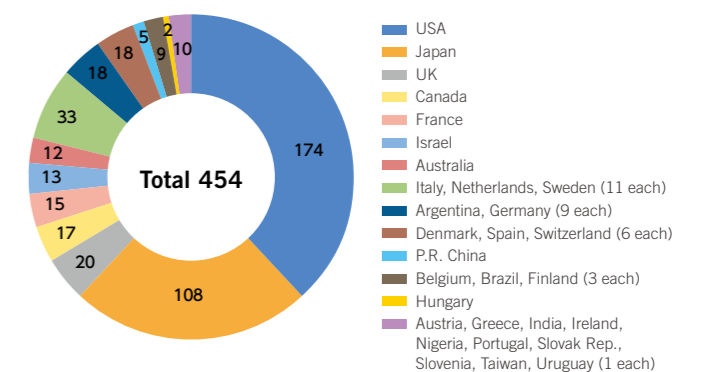
## Support for the Mizutani Foundation for Glycoscience

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

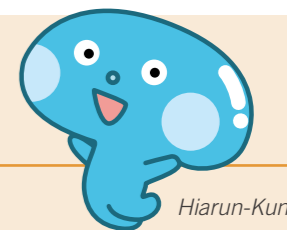
The Mizutani Foundation for Glycoscience, a public interest incorporated foundation, was established in 1992 with an endowment from the late Masakane Mizutani, former president of Seikagaku Corporation, for the purpose of contributing to the welfare of humanity through the advancement and development of glycoscience. The foundation provides research grants to glycoscience researchers in Japan and overseas and supports conferences. In fiscal 2020, the foundation provided research grants totaling ¥70.45 million to 15 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: 1993–2021)



## Promoting early treatment of knee osteoarthritis Hiza Ikiiki (Sprightly Knees), a website for provision of information concerning knee osteoarthritis to the general public



Hiarun-Kun

<https://www.ehiza.jp>

Some 30 million patients\* in Japan are said to suffer from knee osteoarthritis, a disorder marked by knee joint strain due to aging, excessive exercise, or weight increase causing the cartilage to gradually wear away. The *Hiza Ikiiki* website explains basic knowledge concerning knee osteoarthritis, diagnosis, and treatment methods in an easy to understand way and gives information on nearby medical institutions that operate outpatient clinics and provide treatment for knee pain. The pamphlet Exercise Therapy for Knee Osteoarthritis is also available to download.

We will provide correct knowledge to people with knee pain and further enhance website content to enable greater numbers to promptly obtain appropriate treatment.

\* "Locomotive Disorder Countermeasures to Promote Preventive Care," a report from the Ministry of Health, Labour and Welfare issued in 2008



# CONSOLIDATED 10-YEAR SUMMARY

(Millions of yen / %)

	2012/3	2013/3	2014/3	2015/3	2016/3	2017/3	2018/3	2019/3	2020/3	2021/3
Net Sales	27,082	26,639	29,614	29,522	30,962	29,589	30,175	28,384	28,642	27,662
Overseas Sales	6,035	6,311	8,802	9,997	11,581	11,029	12,051	11,966	12,913	13,721
Cost of Sales	9,748	9,867	11,223	12,130	12,871	13,247	13,008	13,114	12,513	12,112
Selling, General and Administrative Expenses	12,716	13,645	13,452	15,008	15,946	15,059	15,745	14,292	14,169	14,018
R&D Expenses	5,970	6,838	6,588	8,146	8,649	7,834	8,408	7,148	6,877	7,209
Operating Income	4,617	3,126	4,937	2,383	2,144	1,282	1,421	977	1,960	1,530
Ordinary Income	4,770	4,302	5,878	4,008	3,500	2,477	5,327	2,859	3,981	3,024
Net Income	3,270	3,256	4,745	3,650	2,578	1,787	3,922	2,244	(10,839)	4,262
Total Equity	58,013	61,316	64,785	70,410	69,815	70,646	73,945	73,036	59,767	63,604
Total Assets	68,730	70,471	73,826	80,889	80,218	80,048	84,098	80,238	68,746	69,915
Overseas Sales Ratio	22.3	23.7	29.7	33.9	37.4	37.3	39.9	42.2	45.1	49.6
Cost of Sales Ratio	36.0	37.0	37.9	41.1	41.6	44.8	43.1	46.2	43.7	43.8
Selling, General and Administrative Expenses Ratio	47.0	51.2	45.4	50.8	51.5	50.9	52.2	50.4	49.5	50.7
R&D Expenses Ratio	22.0	25.7	22.2	27.6	27.9	26.5	27.9	25.2	24.0	26.1
Operating Income Ratio	17.0	11.7	16.7	8.1	6.9	4.3	4.7	3.4	6.8	5.5
Ordinary Income Ratio	17.6	16.1	19.8	13.6	11.3	8.4	17.7	10.1	13.9	10.9
Net Income Ratio	12.1	12.2	16.0	12.4	8.3	6.0	13.0	7.9	—	15.4
Return on Equity (ROE)* <sup>1</sup>	5.7	5.5	7.5	5.4	3.7	2.5	5.4	3.1	(16.3)	6.9
Return on Assets (ROA)* <sup>1</sup>	7.3	6.2	8.1	5.2	4.3	3.1	6.5	3.5	5.3	4.4
Turnover of Total Assets* <sup>1</sup>	0.41	0.38	0.41	0.38	0.38	0.37	0.37	0.35	0.39	0.40
Shareholders' Equity Ratio	84.4	87.0	87.8	87.0	87.0	88.3	87.3	91.0	86.9	91.0
Number of R&D Personnel	221	224	215	216	221	222	233	233	242	231
R&D Personnel Ratio	34.3	34.9	33.6	33.3	33.3	32.3	32.5	31.3	27.9	25.3
Number of Employees	644	641	639	649	663	687	718	744	868	913
Amount of Capital Expenditure	5,718	9,164	7,222	2,095	1,975	1,173	1,591	1,310	2,109	2,127
Depreciation and Amortization	2,008	2,175	1,767	2,610	3,191	2,920	2,925	2,902	1,778	808
Net Income per Share	57.58	57.33	83.55	64.27	45.39	31.55	69.30	39.76	(192.15)	75.54
Total Equity per Share	1,021.24	1,079.38	1,140.48	1,239.51	1,229.05	1,248.07	1,306.37	1,294.88	1,059.40	1,127.14
Dividends per Share	25.00	25.00	26.00	26.00	26.00	31.00* <sup>2</sup>	26.00	26.00	26.00	24.00* <sup>3</sup>
Dividend Payout Ratio	43.4	43.6	31.1	40.5	57.3	98.3	37.5	65.4	—	31.8
Dividends as a Percentage of Total Equity (DOE)	2.5	2.4	2.3	2.2	2.1	2.5	2.0	2.0	2.2	2.2

\*<sup>1</sup> Total Equity and Total Assets are average amounts of the numbers for the end of previous FY and the end of current FY, respectively.

\*<sup>2</sup> Including a 70th anniversary commemorative dividend of ¥5 per share.

\*<sup>3</sup> Including a JOYCLU approval commemorative dividend of ¥4 per share.



Overall net sales and income

In the fiscal year ended March 31, 2021 (fiscal 2020), net sales were ¥27,662 million, down 3.4% year on year. The result is attributable to lower sales from the pharmaceuticals business due to the impact of National Health Insurance (NHI) drug price reductions in Japan coupled with reduced outpatient services in response to COVID-19 infections, despite the positive impact on sales of the consolidation of Dalton Chemical Laboratories, Inc. as a wholly owned subsidiary in March 2020. The overseas sales ratio was 49.6%, an increase of 4.5 points from the previous fiscal year.

Operating income fell 21.9% year on year to ¥1,530 million as a result of the sales decrease and an increase in R&D expenses attributable to costs related to an additional clinical study underway in the U.S. for SI-6603, a treatment for lumbar disc herniation. This occurred despite lower operating expenses, reflecting factors including a decrease in depreciation due to non-recurrence of an impairment loss recognized in the previous fiscal year and a review of sales promotion expenses. Ordinary income fell 24.0% year on year to ¥3,024 million, reflecting a sharp decline in royalty income. Net income attributable to owners of parent was ¥4,262 million, due to corporate tax adjustments of negative ¥1,561 million in connection with recognition of deferred tax assets, taking into consideration the future earnings trend in light of a projected increase in royalty income in the fiscal 2021 and other circumstances.

	2020/3	2021/3	Year on Year
Net Sales	28,642	27,662	-3.4%
Operating Income	1,960	1,530	-21.9%
Ordinary Income	3,981	3,024	-24.0%
Net Income	(10,839)	4,262	—
R&D Expenses	6,877	7,209	+4.8%

Net sales by segment

Pharmaceuticals business

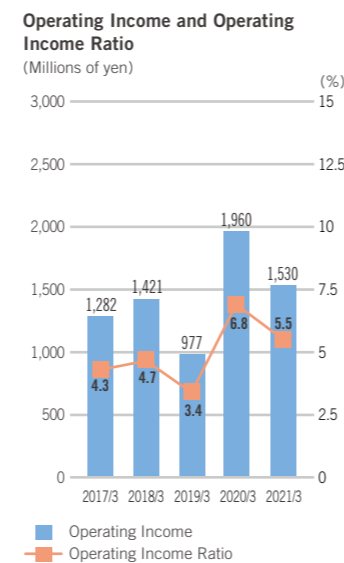
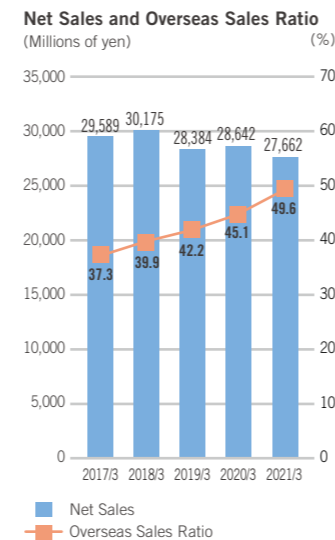
The Pharmaceuticals business is the core business of our company, which manufactures and sells pharmaceuticals, medical devices, and bulk products based on glycoconjugates such as hyaluronic acid. In the Pharmaceuticals business, net sales decreased 6.5% year on year to ¥20,720 million, accounting for 74.9% of total sales.

● Domestic Pharmaceuticals (¥12,019 million, down 12.1% year on year)

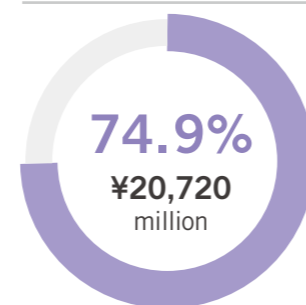
A decrease in outpatient services accompanying COVID-19 contracted the market for ARTZ, a joint function improving agent for knee osteoarthritis, and lower deliveries to medical institutions compared to the previous fiscal year. Even so, switching from competing products to ARTZ progressed, and market share increased, reflecting factors including continued measures to acquire new user facilities. The Company's sales declined sharply, due in part to the impact of NHI drug price reductions.

Although the overall market for the OPEGAN series of ophthalmic viscoelastic devices contracted amid a decrease in the number of cataract surgeries in connection with the spread of COVID-19 infections, deliveries to medical institutions and market share increased due to the impact of shipment adjustments for competing products. The Company's sales were at the prior-year level as the higher volume compensated for the impact of NHI drug price reductions.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, declined on a low-price sales offensive for competing products and fewer



Pharmaceuticals Business Sales Composition



endoscopic surgeries following the spread of COVID-19 infections.

Deliveries to medical institutions of HERNICORE, a treatment for lumbar disc herniation, were at the prior-year level due to a decrease in outpatient services accompanying the spread of COVID-19 infections, despite steady growth in the number of new user facilities. The Company's sales rose due to shipment timing.

● Overseas Pharmaceuticals (¥6,854 million, down 8.2% year on year)

Amid a deep slump in the market overall for Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, due to factors such as postponement of non-urgent and non-emergency medical procedures in connection with the spread of COVID-19 infections, local sales volume in the U.S. increased due to factors including continuation of the trend in the U.S. market toward preference for products that require a low number of injections and successful measures implemented by the sales partner to promote switching from competing products. The Company's sales fell, reflecting the substantial impact of lower shipments accompanying the spread of COVID-19 infections in the first quarter.

Local sales volume in the U.S. and the Company's sales of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, declined due to the continuing preference in the U.S. market for products that require a low number of injections coupled with a decrease in outpatient services.

The U.S. market is recovering with rising economic activity.

Local sales in China of ARTZ were low in the previous fiscal year, impacted by the spread of COVID-19 infection from January to March 2020. The market has recovered steadily from April 2020, and local sales volume and the Company's sales increased.

● Bulk Products and CDMO (contract development and manufacturing organization)\* (¥1,846 million, up 81.0% year on year)

Although sales of bulk products declined, overall sales increased due to the addition of sales from contract development and manufacturing at Dalton Chemical Laboratories, Inc.

\*Starting from the second quarter, the sales of Dalton Chemical Laboratories, Inc., which became a subsidiary in March 2020, are included in the pharmaceuticals business segment.

LAL business

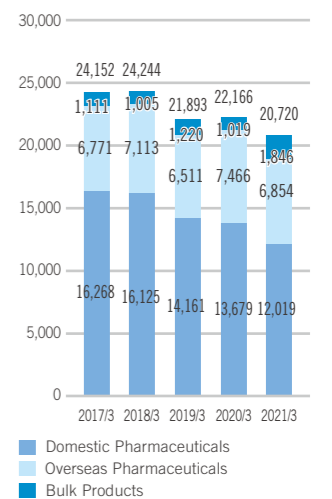
We manufacture and sell endotoxin-detecting reagents used in the quality control of pharmaceuticals and medical devices in Japan and overseas. Net sales of LAL business for the fiscal year under review were ¥6,941 million, up 7.2% from the previous fiscal year.

● LAL Business

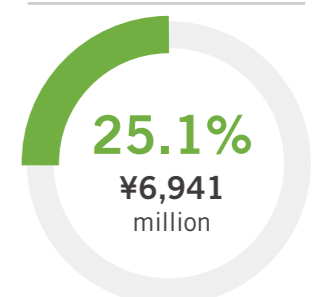
Sales of Bacterial Endotoxin Testing (BET) reagents and Clinical Diagnostic (Fungitell) reagents increased thanks to reinforcement of sales activities at overseas subsidiary Associates of Cape Cod, Inc., coupled with steady sales in Japan.

Sales by Segment	2020/3	2021/3	Year on Year
Pharmaceuticals Business	22,166	20,720	-6.5%
Domestic Pharmaceuticals	13,679	12,019	-12.1%
Overseas Pharmaceuticals	7,466	6,854	-8.2%
Bulk Products and CDMO	1,019	1,846	+81.0%
LAL Business	6,476	6,941	+7.2%
<b>Total</b>	<b>28,642</b>	<b>27,662</b>	<b>-3.4%</b>
(Overseas Sales)	12,913	13,721	+6.3%

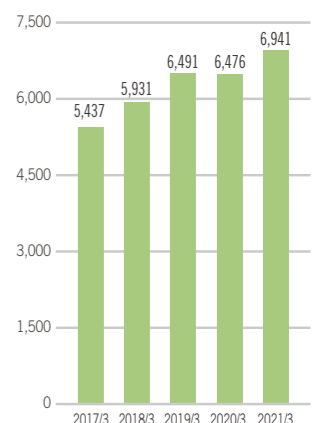
Sales of Pharmaceuticals Business (Millions of yen)



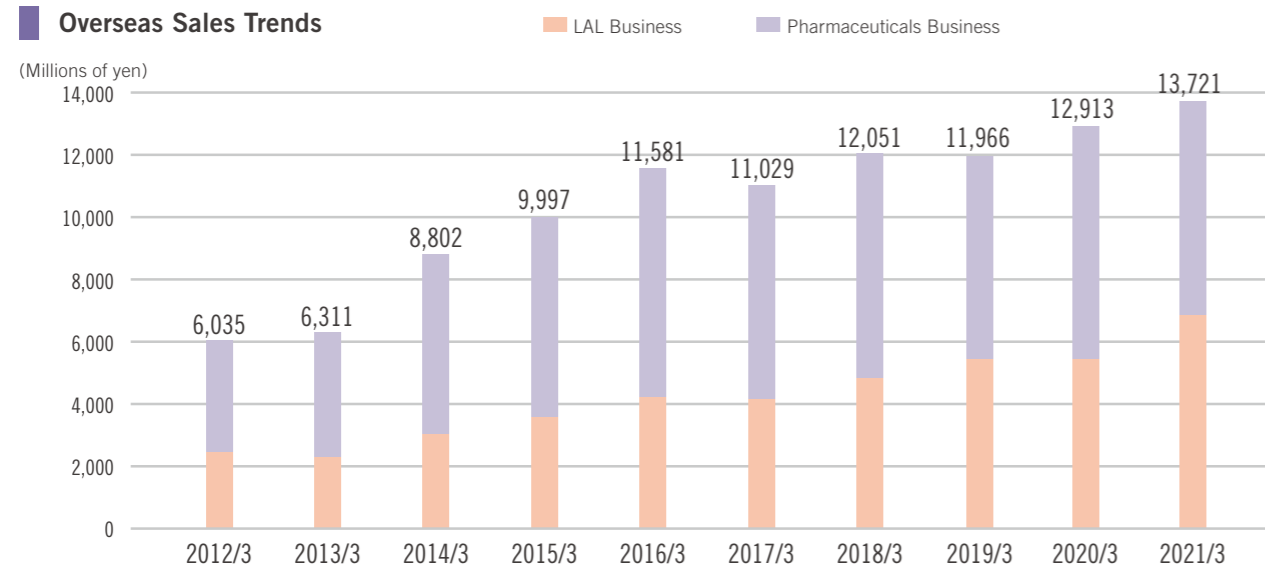
LAL Business Sales Composition



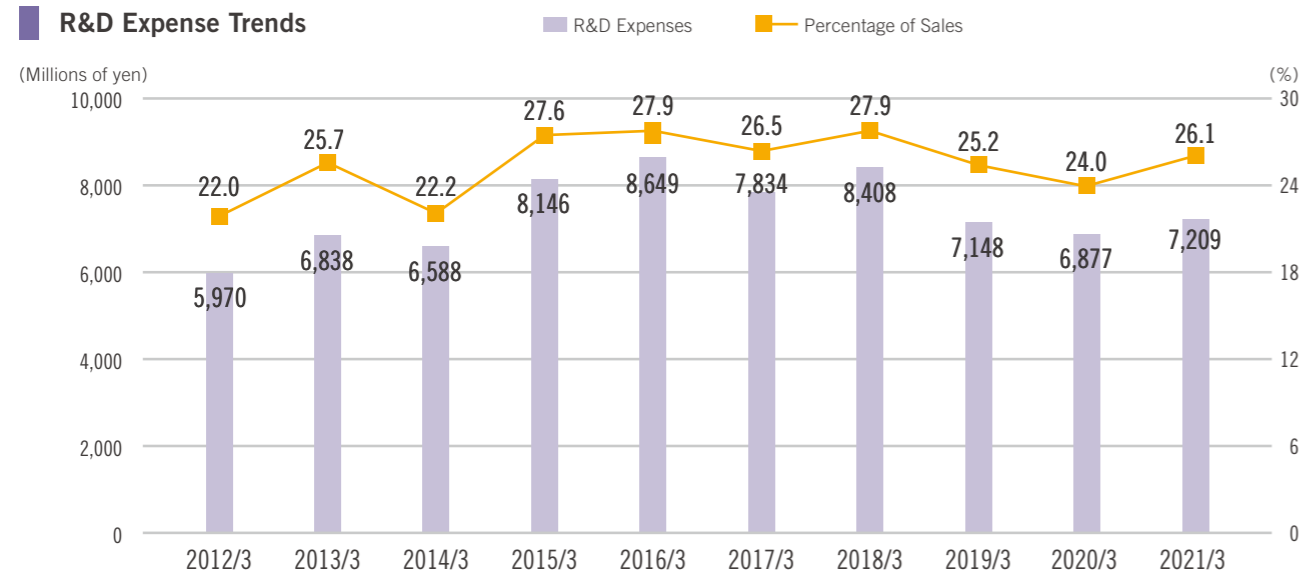
Sales of LAL Business (Millions of yen)



## Overseas Sales Trends

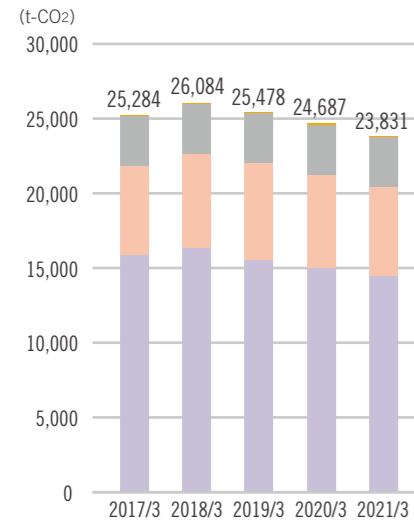


## R&D Expense Trends

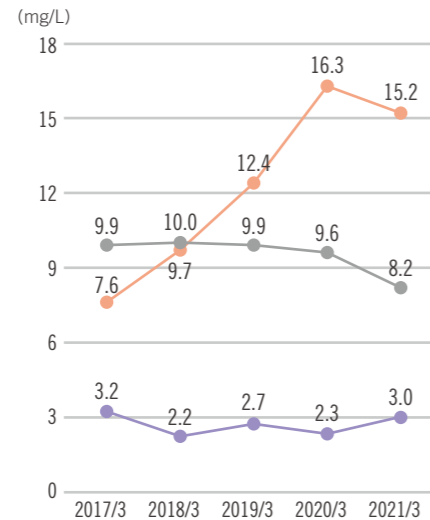


## Non-financial Highlights (Non-consolidated Basis)

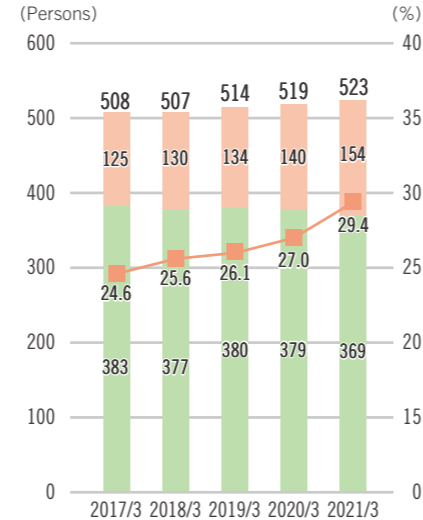
### CO<sub>2</sub> Emissions



### Water Pollution Load (COD)



### Composition of Workforce



■ Takahagi Plant  
■ Kurihama Plant  
■ Central Research / CMC Laboratories  
■ Head Office

■ Males  
■ Females  
■ Percentage of Female Employees  
 Note: Excluding contract employees

## 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. It was established in 1974, became a Seikagaku subsidiary in 1997, and currently plays a central role in the global Bacterial Endotoxin Testing (BET) and clinical glucan detection sectors. ACC employs approximately 250 employees and has operations in the U.K. and Germany.

ACC's reagent 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 that location, ACC also offers customers in-house contract testing services for BET and clinical glucan product testing.

### Corporate Outline (As of March 31, 2021)

Paid-in Capital	\$2,080
Ownership Ratio	100%
Business	Manufacturing and sales of reagents
URL	<a href="https://www.acciusa.com">https://www.acciusa.com</a>



## Dalton Chemical Laboratories, Inc. (Ontario, Canada)

Dalton Chemical Laboratories, Inc., 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. Dalton was established in 1986 and has a U.S. and Canadian GMP<sup>\*1</sup>-compliant manufacturing site for pharmaceuticals and other products in Ontario, Canada. Dalton currently has approximately 150 employees.

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

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

### Corporate Outline (As of March 31, 2021)

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

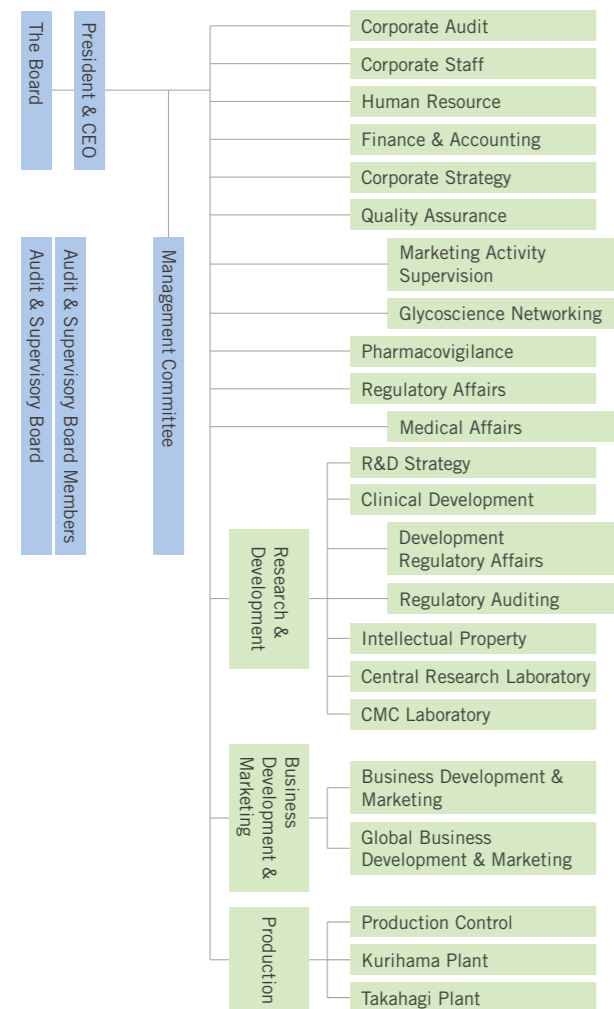


\*2 Dalton is a wholly owned subsidiary of SKK CANADA ENTERPRISES CORPORATION, an intermediate holding company established in Canada by Seikagaku.

**Overview** (As of March 31, 2021)

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, First Section (Stock code: 4548)
URL	https://www.seikagaku.co.jp/en/
Number of Employees	913 (Consolidated)
Paid-in Capital	¥3,840 million
Net Sales	¥27,662 million (As of March 31, 2021)

**Organization Chart** (As of March 31, 2021)



- General Marketing Compliance Manager
- Quality Assurance Manager
- Safety Management Manager

**Locations**

<b>Head Office</b>	Marunouchi Center Building 6-1, Marunouchi 1-chome Chiyoda-ku Tokyo 100-0005, Japan Tel: (81) 3-5220-8950
<b>Central Research Laboratory/ CMC Laboratory</b>	1253, Tateno 3-chome Higashiyamato-shi Tokyo 207-0021, Japan Tel: (81) 42-563-5811
<b>Kurihama Plant</b>	3-1, Kurihama 9-chome Yokosuka-shi Kanagawa 239-0831, Japan Tel: (81) 46-835-3311
<b>Takahagi Plant</b>	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** (As of March 31, 2021)

Shares per Unit	100
Authorized Shares	234,000,000
Authorized Outstanding Shares	56,814,093
Number of Shareholders	9,654
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)

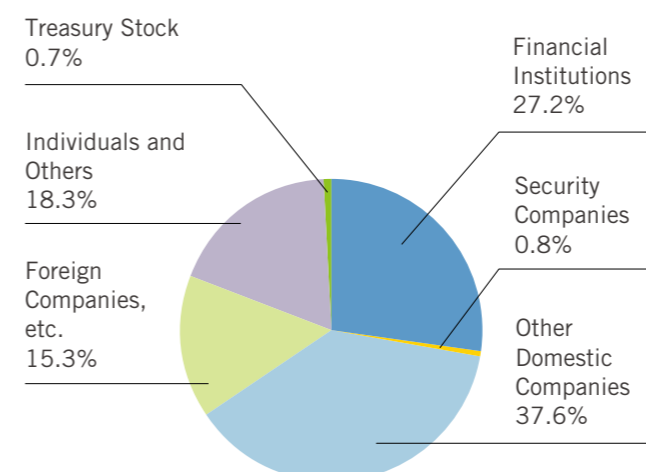
**Major Shareholders** (As of March 31, 2021)

Name of Shareholders	Number of Shares Held (Thousands of Shares)	Percentage of Outstanding Shares (%)
1 Shingyo KK	7,843	13.9
2 KK Kaiseisha	7,293	12.9
3 The Master Trust Bank of Japan, Ltd. (Trust account)	4,179	7.4
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.	1,973	3.5
5 Custody Bank of Japan, Ltd. (Trust account 9)	1,719	3.0
6 MUFG Bank, Ltd.	1,536	2.7
7 The Bank of New York Mellon (International) Limited 131800	1,491	2.6
8 Kaken Pharmaceutical Co., Ltd.	1,207	2.1
9 Custody Bank of Japan, Ltd. (Trust account)	1,204	2.1
10 Mizutani Foundation for Glycoscience	828	1.5

Note: Treasury stock (384 thousand shares) is excluded from the calculations of the percentages above.

**Breakdown of Shareholders by Type**

(As of March 31, 2021)



**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/>