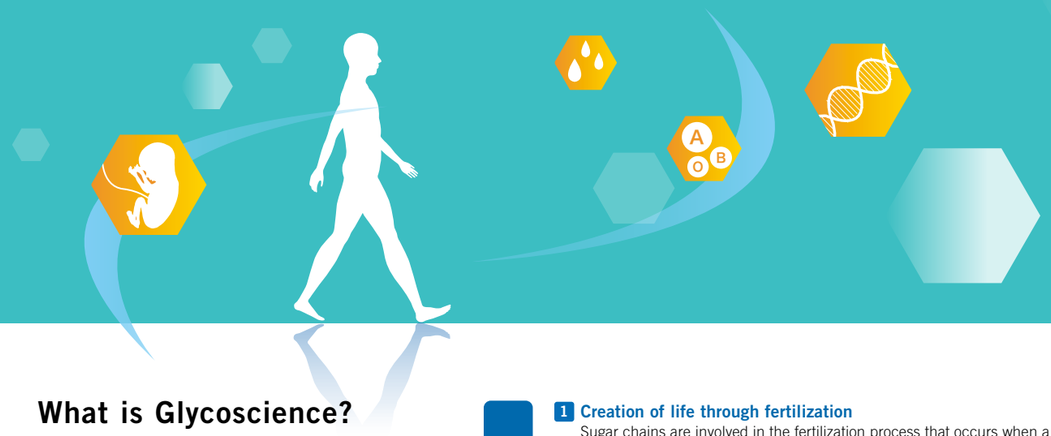
SEIKAGAKU CORPORATE REPORT 2019

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 controls 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 one-third of our employees are involved in R&D.

≪ Editorial Policy ≫

The Seikagaku Corporate Report 2019 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 2018 (April 1, 2018–March 31, 2019), but it also includes references to activities in fiscal 2019.

Contents

OUR HISTORY

Success Based on Steady Pursuit of a Unique Vision

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

1940s~
The world's first company to successfully produce chondroitin sulfate on a commercial scale.

1970s~
Pharmaceuticals using hyaluronic acid are developed.

1990s~
Enhances its range of pharmaceuticals using hyaluronic acid and expands its activities in overseas markets.

2018~
Product diversification leveraging cutting-edge glycoscience technology. Toward a new stage.

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

1992
Launch of ARTZ® in Sweden under the name "Artzal®," making the start of full-scale overseas marketing of ARTZ®

1993
Launch of ARTZ Dispo®

1995
Launch of OPEGAN Hi®

2001
Launch of ARTZ® in the U.S. under the name "SUPARTZ®" (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

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).

Innovating Novel Contributions and Approaches

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

Social issues

- Unmet medical needs*
  - *Situations in which healthcare needs are not met or there are healthcare needs relating to diseases for which there are no effective treatment methods.
- Super-aging society
- Rising healthcare costs
- Locomotive syndrome
  - *Locomotive syndrome: Reduced mobility due to disorders affecting locomotion, such as the knee joints and hip joints—These disorders are regarded as one of the factors that can reduce healthy life expectancy.

Assets

Human capital
Highly qualified personnel

Intellectual capital
Compound library and advanced knowledge relating to glycoscience

Manufacturing capital
Production and quality control systems to ensure the reliable supply of products

Financial capital
A stable financial base as a source of funding for drug discovery

Sources of competitiveness

Specialization in R&D and manufacturing
- Lean organizational structure with no pharmaceutical marketing units
- R&D investment equivalent to 25-30% of net sales

Glycoscience

State-of-the-Art Technology related to GAG
- Advanced manufacturing basic technologies, including extraction, purification, cultivation and modification technologies
- The ability to create diverse new pharmaceuticals based on the use of GAG and related enzymes

*GAG: Glycosaminoglycans (one of the components of glycoconjugates), such as hyaluronic acid and chondroitin sulfate

Output
Products and services

Innovative, high-quality pharmaceuticals and medical devices, etc.

《Ethical pharmaceuticals, medical devices》

Seikagaku contributes to healthcare in Japan and overseas by supplying ethical pharmaceuticals and medical devices based on GAG, such as hyaluronic acid and chondroitin sulfate, which are both structural components of glycoconjugates, and enzymes that act on GAG.

<Products for the treatment of orthopedic disorders>
- ARTZ® series: Joint function improving agent
- GEL-ONE®: Intra-articular single-injection viscosupplement
- HERNICORE®: Treatment for lumbar disc herniation

<Ophthalmic products>
- OPEGAN®, OPEGAN Hi®: Ophthalmic viscoelastic device
- SHELLGAN®: Ophthalmic viscoelastic device

<Other products>
- MucoUp®: Submucosal injection agent for endoscopic surgery
- Bulk product: Sodium hyaluronate, sodium chondroitin sulfate

《LAL-related products》

Seikagaku supplies endotoxin-detecting reagents and other products to pharmaceutical manufacturers, primarily for use in quality control in manufacturing processes for pharmaceuticals and medical devices.
- Endotoxin-detecting reagents
- Endotoxin-detecting equipment

P11

Business flow

R&D P15 → Production P21 → Marketing (through sales partners) P23 → Medical institutions / Patients

Quality compliance P25

Business risks

- Healthcare system reforms (including drug price system changes)
- Reliance on specific distributors and products
- Time and expense required for new drug development
- Procurement of animal-derived substances and restrictions on their use

P35

Outcome

Value Proposition

Improvement of patients' quality of life (QOL)

Extension of healthy life expectancy

Minimization of treatment impacts on patients

Further development and advancement of glycoscience

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.

Contributing to medical care globally as an R&D-based pharmaceutical manufacturer specializing in glycoscience

Guided by the motto “Creativity, Fairness, Dreams and Passion,” Seikagaku Corporation aims to live up to our Creed: “Under the principle of respect for learning, we contribute to human well-being by creating and supplying the world with safe and useful pharmaceutical products based on glycoscience.”

Ever since its founding in 1947, Seikagaku has maintained a stance of focusing on research and development, and we contribute to medical care globally by developing and supplying pharmaceuticals and medical devices such as ARTZ, the world’s first joint function improving agent using hyaluronic acid.

It is becoming understood that sugar chains and glycoconjugates, Seikagaku’s area of expertise, are deeply involved in a variety of life phenomenon, and the potential role of glycoscience in the field of drug discovery has greatly expanded in recent years. We will continue to make optimal use of the glycoscience knowledge and technology accumulated by Seikagaku over many years as we take up the challenge of helping patients everywhere to enjoy health and well-being by supplying new drugs to meet real needs.

PRESIDENT'S MESSAGE

Overview of the previous mid-term management plan

We formulated the Seikagaku Corporation Ten-Year Vision in 2009. Under a three-year mid-term management plan launched in April 2016 as the final step in accomplishing the Ten-Year Vision, we have implemented four high-priority initiatives. I will now discuss the results of the previous mid-term management plan, completed in the fiscal year ended March 31, 2019 (fiscal 2018), and remaining issues.

Launch of HERNICORE in Japan and progress with its development in the U.S.

The first high-priority initiative in the management plan was to develop of SI-6603, a treatment for lumbar disc herniation. In August 2018 we launched HERNICORE® 1.25 Units for Intradiscal Injection in Japan through our sales partner Kaken Pharmaceutical Co., Ltd. Since HERNICORE is the first drug to be classified as intradiscal enzyme injection therapy into a lumbar disc in Japan, strict requirements for use have been set. Since the launch, we have worked to implement a phased rollout, paying careful attention to promoting appropriate use and safety assurance. As SI-6603 development progressed in the U.S., the primary endpoint of a Phase III clinical study was not met, and we are now conducting an additional Phase III clinical study initiated in February 2018. We will raise the probability of success by focusing on a variety of measures that apply knowledge gained from the previous study.

Current situation in the knee osteoarthritis market and development of next-generation products

I will now review the second high-priority initiative, which was development of the knee osteoarthritis market. The U.S. market for hyaluronic acid injectable treatments began to contract on a value basis in 2018 due to the impact of intensifying competition and suspension of reimbursement by some insurance companies. In these circumstances, although local sales volume of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, has steadily increased, volume has fallen short of our target due to the adverse market environment. At the same time, we have made progress developing new markets for single-injection products, and in March 2019, we launched HyLink in Italy through sales partner MDM S.p.A.

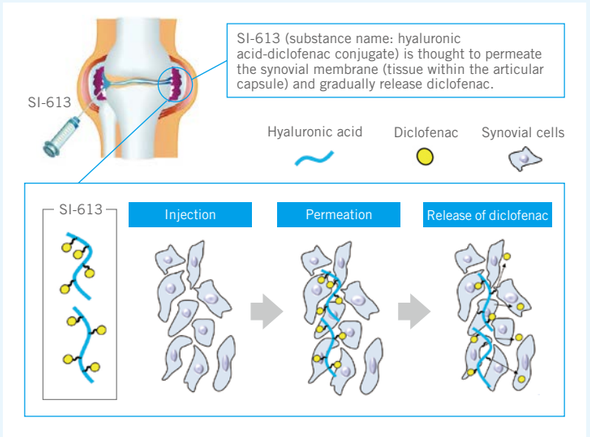
We have been able to maintain the level of deliveries to medical institutions of ARTZ, a joint function improving agent sold in Japan, thanks to active implementation of product modifications, and market share is steadily increasing. Nevertheless, Seikagaku's sales declined sharply in fiscal year 2018 because of the impact of National Health Insurance (NHI) drug price reduction resulting from drastic reform of the drug price system.

Development status of SI-613 (treatment for osteoarthritis)

SI-613 is a new osteoarthritis treatment in which hyaluronic acid and diclofenac (an anti-inflammatory drug) are chemically bound. Since SI-613 combines the pain relief and anti-inflammatory effect of diclofenac, which is designed for sustained release (see the illustration to the right), with the joint function improving effect of hyaluronic acid, it is expected to provide prompt and sustained relief of the pain and inflammation associated with osteoarthritis. Further, since SI-613 is administered directly into the joint cavity as an injectable treatment, systemic exposure to diclofenac is low, and the risk of systemic side effects is also thought to be low.

Seikagaku is currently developing SI-613 in Japan and the U.S., partnering with Ono Pharmaceutical Co., Ltd. for co-development in Japan. Three Phase III clinical studies are currently in progress. A primary endpoint of a confirmatory study in patients with knee osteoarthritis has been met. Follow-up observation in a study on osteoarthritis of other joints (four sites) was completed in June of this year, and the data obtained is currently being analyzed. We will aim to apply for the manufacturing and marketing approval in the first half of 2020 following consideration of the results of the three studies.

Sustained release of diclofenac in SI-613



In these circumstances, we are focusing on development of SI-613, a treatment for the osteoarthritis, as a next-generation product. In Japan, we have reached the final stage of a Phase II clinical study and aim to apply for the manufacturing and marketing approval in the first half of 2020. We have concluded with Ono Pharmaceutical Co., Ltd. an agreement on co-development and marketing collaboration of SI-613 in Japan. We have put in place a development structure in cooperation with Ono Pharmaceutical and are striving to obtain approval at an early date. In addition, we plan to receive milestone royalties from Ono Pharmaceutical in accordance with future progress in development and marketing.

Enhancement of the development pipeline

The third high-priority initiative was enhancement of the development pipeline. In May 2018, we added a new development theme to the pipeline by initiating a clinical study in Japan of SI-449, an adhesion barrier developed using our own glycosaminoglycan cross-linking technology. We estimate the size of the global market for adhesion barriers to be approximately ¥100 billion. Going forward, we will continue to focus on the clinical study underway in Japan and aim for development on a global scale to promote use for greater numbers of patients.

Other development themes we aim to move to the clinical study stage also progressed, and our initiatives to expand and enhance our development pipeline advanced.

Pursuit of an optimal production and quality management systems

The fourth high-priority strategy was pursuit of optimal production and quality management systems. To continuously provide high-quality products, we further strengthened control systems compliant with global standards by upgrading manufacturing facilities and introducing a new quality control system. We also engaged the services of expert consultants and implemented at our production sites operational improvements to boost production efficiency and product cost reduction measures that involved cutting various costs.

Under the previous mid-term management plan, we achieved results that included the launch in Japan of HERNICORE, a treatment for lumbar disc herniation; progress in developing new drugs, notably SI-613, a treatment for osteoarthritis; and growth in the LAL business. At the same time, the need to respond to changes in the business environment, such as drastic reform of the drug price system in Japan and intensification of competition in overseas markets, remained an urgent issue.

Essential features of the next mid-term management plan

We have settled on the essential features of the next mid-term management plan, in which we have made addressing issues remaining after completion of the previous management plan the main focus.

Since securing a new earnings foundation is an urgent task, in the core Pharmaceuticals business we will concentrate our efforts on ensuring the success of HERNICORE, SI-6603 (a treatment for lumbar disc herniation) in the U.S., and SI-613 (a treatment for osteoarthritis) as pillars of the business. In the LAL business, we will accelerate expansion into the worldwide market of endotoxin-detecting reagents utilizing gene recombination technology in cooperation with subsidiary Associates of Cape Cod (ACC). We will also work to earn model diversification, unconstrained by the traditional business model. On the basis of these measures, we will rigorously pursue reduction of various costs and implement an agile management strategy that utilizes our financial foundation.

In the area of R&D, the source of growth, we will continue to position glycoscience at the core of drug discovery and enhance the development pipeline. Furthermore, we will increase R&D efficiency and strive to rapidly and continuously originate new drugs that people truly need by utilizing basic technologies, such as drug delivery systems (DDS) that apply glycoscience and pursuing an open innovation strategy in collaboration with other companies, universities, and research institutions.

To Our Stakeholders

The environment surrounding the pharmaceutical industry is likely to become even more adverse. Seikagaku will mount an all-out, company-wide effort to build a robust earnings foundation and return to a growth trajectory under an agile management strategy.

Also, we are keenly aware of our social mission and responsibilities as a pharmaceutical manufacturer and will aim for sustained improvement of corporate value by striving to rigorously practice honest corporate activities, to ensure management transparency, and to strengthen corporate governance on the basis of high ethical standards.

We look forward to the continuing guidance and support of our stakeholders.

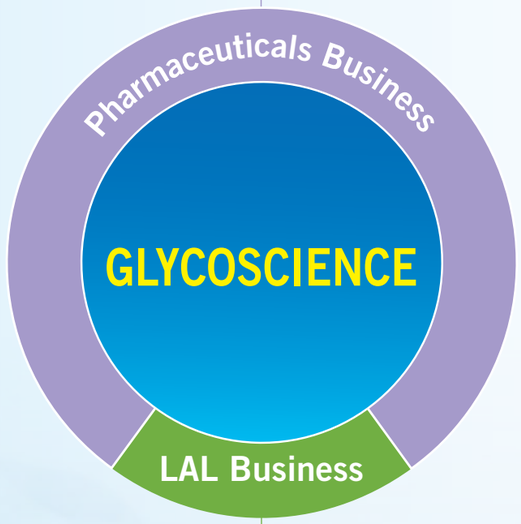
President & CEO
Ken Mizutani

BUSINESS ACTIVITIES AND PRODUCTS

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

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.



LAL Business

In addition to the Pharmaceuticals business, Seikagaku has LAL business which provides endotoxin-detecting reagents and other related products.

What is the LAL business?

The main products of the LAL business are endotoxin-detecting reagents made from limulus amebocyte lysate (LAL), a substance extracted from the blood cells of horseshoe crabs.

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.

Joint Function Improving Agents

ARTZ®, ARTZ Dispo®, SUPARTZ FX®*1, VISCO-3™

ARTZ, a vial, containing hyaluronic acid as its main active pharmaceutical ingredient, became the world's first joint function improving agent. ARTZ Dispo is a prefilled syringe product*2 that saves the step of aspirating the drug solution into a syringe. These products have been approved and are supplied not only in Japan but also in overseas markets, including the U.S., Asia, and Europe.

*1 SUPARTZ FX is sold in the U.S. under its brand name *2 A kit with injectable syringe that have the solution been filled.

ARTZ Dispo®

SUPARTZ FX®

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 3 mL 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.


Gel-One®

Treatment for Lumbar Disc Herniation

HERNICORE®

HERNICORE, which contains enzyme named "condoliase" as its active pharmaceutical ingredient, is Japan's first product for the treatment of lumbar disc herniation. It can be administered without general anesthesia, and the administration can be less invasive for the patient compared to surgical technique because of direct intradiscal injection.

HERNICORE®

Ophthalmic Viscoelastic Devices (OVD)

OPEGAN®, OPEGAN Hi®, SHELLGAN®

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.*

* Endoscopic Submucosal Dissection/Endoscopic Mucosal Resection

MucoUp®

Bulk Products

Sodium hyaluronate and Sodium chondroitin sulfate

Seikagaku manufactures high-purity and high-quality sodium hyaluronate and sodium chondroitin sulfate with its unique extraction and purification technologies. The bulk products are primarily used as raw materials for pharmaceuticals and cosmetics products.


Bulk products

Endotoxin-detecting Reagents

ENDOSPECY®, TOXICOLOR®, Pyrochrome®, etc.

The Endotoxin-detecting reagents that Seikagaku produces with its own technologies are mainly used in quality control of injectable pharmaceuticals, biological products, and medical devices, manufacturing processes, and water quality control of dialysate used in artificial dialysis.


Endotoxin-detecting reagents

Endotoxin-detecting Devices

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

REVIEW OF OPERATIONS (April 1, 2018 – March 31, 2019)

Overall net sales and income

In the fiscal year ended March 31, 2019 (fiscal 2018), net sales were ¥28,384 million, down 5.9% year on year. The result is attributable to a sharp decline in sales from the Pharmaceuticals business due to the impact of National Health Insurance (NHI) drug price reductions in Japan implemented in April 2018, despite growth from the LAL business in Japan and overseas.

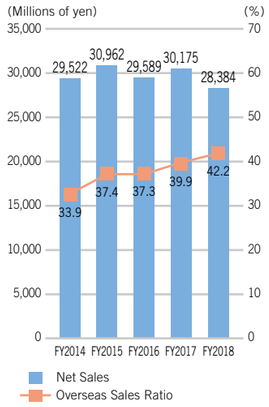
With regard to earnings, although selling, general and administrative expenses, mainly R&D expenses, decreased, operating income fell 31.3% year on year to ¥977 million. Ordinary income fell 46.3% year on year to ¥2,859 million, reflecting a sharp decline in royalty income and other factors, despite an increase in gain on sale of investment securities, and net income attributable to owners of parent fell 42.8% year on year to ¥2,244 million.

Total R&D expenses in fiscal 2018 decreased 15.0% year on year to ¥7,148 million, or 25.2% of net sales.

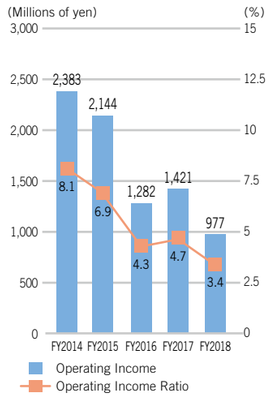
(Millions of yen)

	FY2017	FY2018	Year on Year
Net Sales	30,175	28,384	–5.9%
Operating Income	1,421	977	–31.3%
Ordinary Income	5,327	2,859	–46.3%
Net Income	3,922	2,244	–42.8%
R&D Expenses	8,408	7,418	–15.0%

Net Sales and Overseas Sales Ratio



Operating Income and Operating Income Ratio

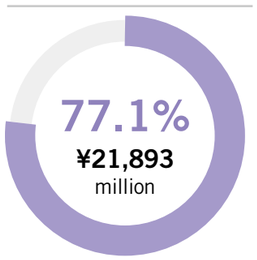


Net sales by segment

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 9.7% year on year to ¥21,893 million, accounting for 77.1% of total sales.

Pharmaceuticals Business Sales Composition



Domestic Pharmaceuticals (¥14,161 million, down 12.2% year on year)

Amid overall market contraction, deliveries to medical institutions and market share of ARTZ, a joint function improving agent, increased thanks to sales expansion measures by the sales partner accompanying the introduction of a modified product that meets user needs. The Company's sales fell sharply, reflecting the impact of NHI drug price reductions implemented in April 2018.

Deliveries to medical institutions and market share of the OPEGAN series of ophthalmic viscoelastic devices increased due to strong performance from SHELLGAN. The Company's sales increased slightly, as the higher deliveries to medical institutions and market share compensated for the impact of NHI drug price reduction.

The Company is striving for a phased rollout of HERNICORE, a treatment for lumbar disc herniation launched in August 2018, by providing information to medical institutions aimed at ensuring appropriate use and safety. Since fiscal 2018 was the launch year, the Company's sales were small.

The Company's sales of MucoUp, a submucosal injection agent for endoscopic surgery, increased slightly.

Overseas Pharmaceuticals (¥6,511 million, down 8.5% year on year)

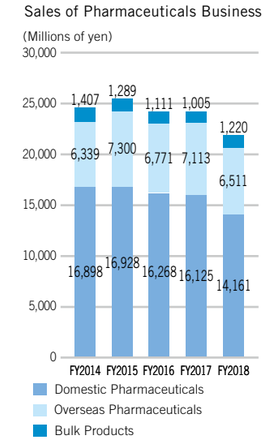
In the U.S., the market for hyaluronic acid injectable treatments began to contract on a value basis due to the impact of factors such as intensifying competition and suspension of reimbursement by some insurance companies. In these circumstances, local sales and the Company's sales of Gel-One, an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, increased thanks to sales expansion measures by the sales partner. Local sales and the Company's sales of SUPARTZ FX, an intra-articular 5-injection viscosupplement for the treatment of knee osteoarthritis, declined sharply, reflecting the strong impact of the suspension of reimbursement requirements.

Local sales of ARTZ in China (P.R.C.) and the Company's sales increased, reflecting successful sales partner sales expansion activities targeting both urban and surrounding areas.

Bulk Products (¥1,220 million, up 21.4% year on year)

Sales of hyaluronic acid and chondroitin sulfate for pharmaceutical companies increased.

Sales of Pharmaceuticals Business



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 ¥6,491 million, up 9.4% from the previous fiscal year.

LAL Business Sales Composition

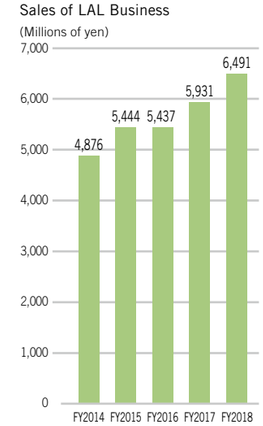
LAL Business

Sales of endotoxin-detecting reagents increased in domestic and overseas markets. Overseas subsidiary Associates of Cape Cod, Inc. is focusing on expanding both direct and distributor-based sales operations, and its sales of bacterial endotoxin testing (BET) reagents and glucan detecting *in vitro* clinical diagnostic reagents are increasing.

(Millions of yen)

Sales by Segment	FY2017	FY2018	Year on Year
Pharmaceuticals Business	24,244	21,893	–9.7%
Domestic Pharmaceuticals	16,125	14,161	–12.2%
Overseas Pharmaceuticals	7,113	6,511	–8.5%
Bulk Products	1,005	1,220	+21.4%
LAL Business	5,931	6,491	+9.4%
Total	30,175	28,384	–5.9%
(Overseas Sales)	12,051	11,966	–0.7%

Sales of LAL Business



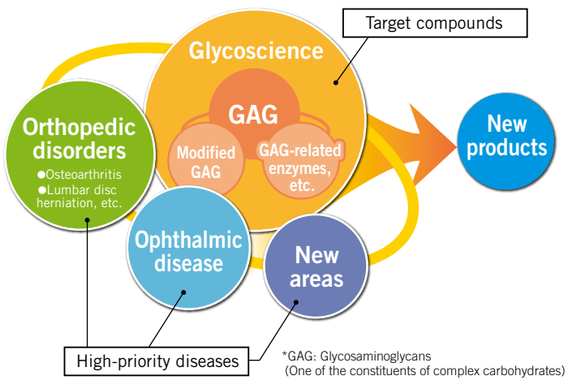
RESEARCH AND DEVELOPMENT

Seikagaku engages in research and development of innovative drugs that 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.



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). GAG exist in living organisms as structural components of glycoconjugates. Sugar chains are known in the life sciences as the third biological chains, along with nucleic acids and proteins. They have complex chemical structures and pose characteristic difficulties in research in areas such as structural analysis, automatic synthesis, and large-scale synthesis.

Some years ago, an industry-government-academia research project focused on glycoscience was formed and its activities advanced the structural analysis and synthesizing technologies for GAG. In addition, the genes of sugar-chain synthesizing enzymes and degrading enzymes have been comprehensively identified, and our understanding of the functions of sugar chains in living organisms is advancing. This progress in glycoscience technologies is closely linked with Seikagaku's drug discovery research.

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 enter new fields. At the same time, we make efforts to maximize the value of our products on the market or schenes 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.

Message from the Head of the Research & Development Division

Seikagaku Corporation's social mission is to continuously create original, innovative pharmaceuticals and medical devices that respond to unmet medical needs using glycoscience-related technologies and expertise accumulated over many years and to provide them to all patients around the world.

In February 2019, a main confirmatory study among three Phase III clinical studies in Japan for SI-613, a treatment for osteoarthritis being developed as the next-generation ARTZ, met its primary endpoint for patients with knee osteoarthritis. We will aim for a new drug application for SI-613 in the first half of 2020 following consideration of the results of the remaining two studies.

We are also proceeding with a Phase III additional clinical study in the U.S. for SI-6603, a treatment for lumbar disc herniation. To increase the probability of success in this study, we have set rigorous criteria in light of the knowledge obtained from the previous study. Although progress with the study is behind schedule, we will focus on various measures to promote subject enrollment.

To achieve our aspiration of being a professional organization of scientists who think carefully about science and generate outcomes, we will continue to steadily advance the development pipeline and strive to create new drug candidates with potential for global development.

Yosuke Funakoshi
Executive Vice President
Head of Research and Development Division

RESEARCH AND DEVELOPMENT

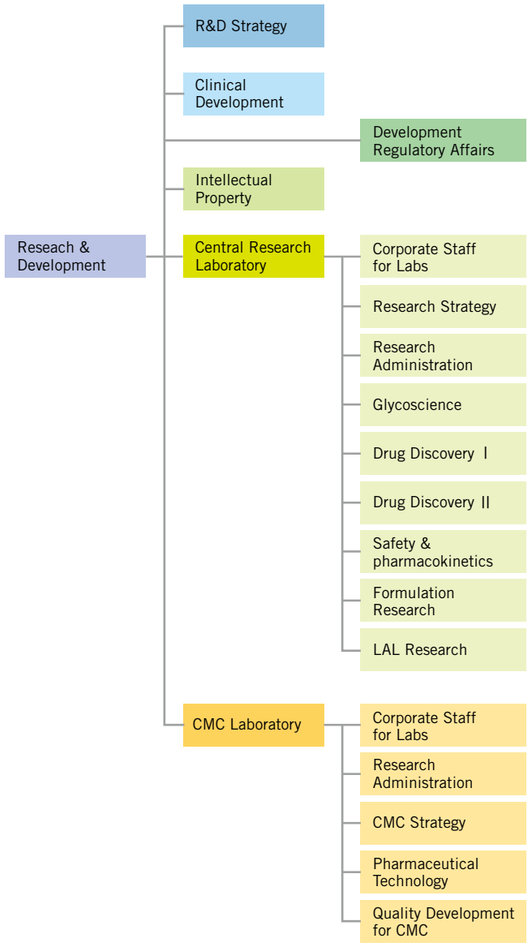
Research and development organization

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.

* CMC is an abbreviation for Chemistry, Manufacturing and Controls, which refers to the physicochemical properties and standards of active pharmaceutical ingredients (API) and formulations, their manufacturing processes, and quality control.

Research & Development Division Structure

(As of January 1, 2020)



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 (glycosaminoglycan) and related compounds as pharmaceutical candidate substances
- Drug Discovery: Synthesis of new candidate substances, efficacy evaluation, and research on the mechanisms of action
- Safety & Pharmacokinetics: Evaluation of pharmacokinetics and toxicity profiles of candidate substances *in vivo*
- Formulation Research: Exploratory formulation research by basic physicochemical examination

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

Central Research Laboratory / CMC Laboratory

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, knowhow, etc.) and their protection. It works closely with Research and 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.

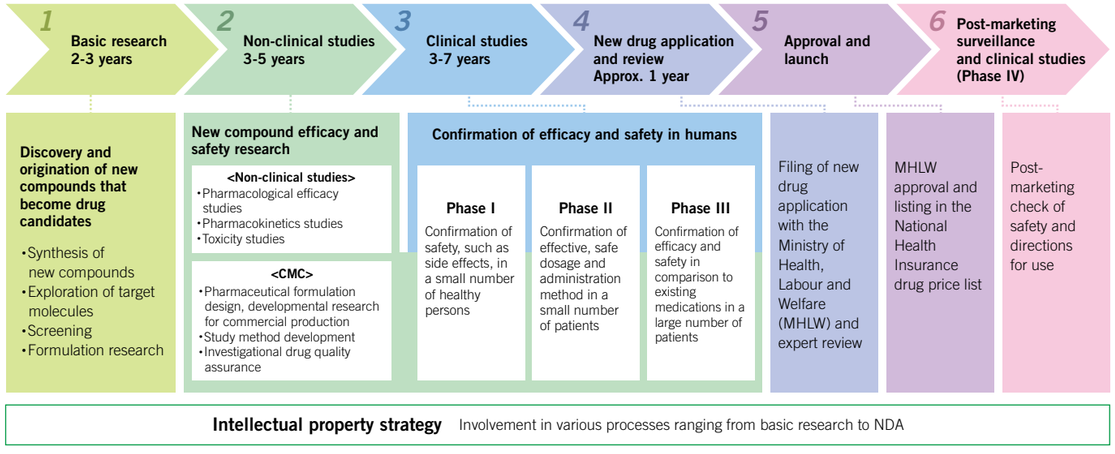
Ordinarily, more than ten years is required from discovery of a candidate substance until its approval as a new drug. Within the long, difficult new drug development process, clinical development is considered to hold the key to whether an NDA can be filed.

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.

* Ethical Guidelines for Human Genome and Genetic Sequencing Research and Ethical Guidelines for Medical and Health Research Involving Human Subjects

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 with the 3Rs Principle by the Japan Health Sciences Foundation's Center for Accreditation of Laboratory Animal Care and Use, 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)

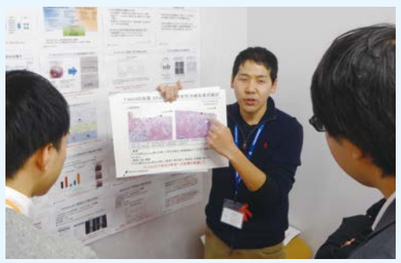
Topics

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. There were 42 entries at the forum in fiscal 2018. In addition to young and mid-career researchers, employees from other business sites participated, actively discussing the future potential and contribution to medical needs of each research theme. Employees who submitted entries expressed their ambitious enthusiasm with comments such as, "I want to press ahead with my research so that someday I will be able to propose a drug-discovery technology unique to Seikagaku" and "I want to increase the feasibility of my research by seriously grappling with the issues and information presented at the forum."

By deepening interaction among employees through the exchange of ideas and information sharing, and contributing to the enhancement of Seikagaku's R&D and technological capabilities, we aim to originate and create development themes, such as new pharmaceuticals that people truly need.

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



A researcher enthusiastically explaining his research at a poster session

Researchers receiving the Head of Research and Development Division's Award and the Head of Central Research Laboratory Director's Award

Development Pipeline

[Pharmaceuticals]

(As of October 1, 2019)

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	Osteoarthritis	Japan				
		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	

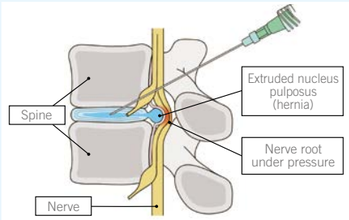
[Medical Devices]

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

SI-6603 (treatment for lumbar disc herniation)

SI-6603, which contains condoliase as its active pharmaceutical ingredient, is a treatment for lumbar disc herniation. Since it is a treatment directly injected into the intervertebral disc, it does not require a general anesthesia and is 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 result, Seikagaku initiated an additional Phase III clinical study in February 2018.



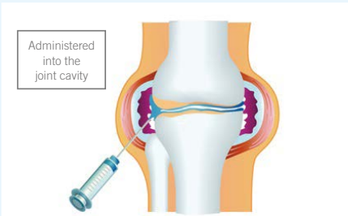
Administration of SI-6603

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. Since SI-613 combines the pain relief and anti-inflammatory effect of a diclofenac formulation designed for sustained release with the joint function improving effect of hyaluronic acid, it is expected to provide prompt and long-lasting relief of the pain and inflammation associated with osteoarthritis and enthesopathy.

In Japan, a confirmatory study of SI-613 (osteoarthritis) in patients with knee osteoarthritis, one of three Phase III clinical studies, met its primary endpoint. We will aim for a new drug application in the first half of 2020 following consideration of the results of the other two studies: a clinical study on osteoarthritis of four other sites and a long-term administration study.

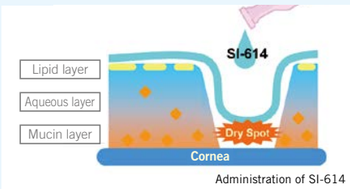
Follow-up observation has been completed in a late-stage Phase II clinical trial in Japan for SI-613-ETP (enthesopathy) and a Phase II clinical trial in the U.S. for SI-613 (knee osteoarthritis), and Seikagaku is currently analyzing the data obtained from these studies.



Administration of SI-613

SI-614 (treatment for dry eye)

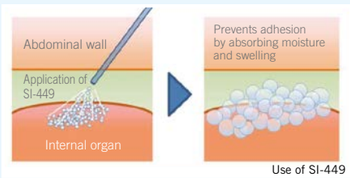
SI-614, an ophthalmic solution, is a modified hyaluronate produced using Seikagaku's proprietary technology. Ocular instillation of SI-614 is expected to protect the ocular surface and promote corneal wound healing. A Phase II/III clinical study was completed in January 2015, and Seikagaku is currently proceeding with selection of a co-development and sales partner.



Administration of SI-614

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. Since it is a powdered formulation, it adheres well to uneven tissue surfaces. It is thought to offer excellent utility in laparoscopic surgery, an increasingly common surgical procedure. Seikagaku initiated a pilot study in May 2018 and will proceed with development with a view to global introduction.



Use of SI-449

PRODUCTION

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

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. We are also working to improve production efficiency through periodic checking and improvement of manufacturing processes using computerized systems for manufacturing and quality control. 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 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.

We have also established the group-wide Energy Conservation Promotion Committee and are engaging in group-level initiatives to save energy, such as information sharing and joint consideration of improvement measures among the Group's business sites.

Topics

Kurihama Plant improvement project and 5S activities

The Kurihama Plant is implementing operational improvement activities focused mainly on improving work efficiency and reducing the burden on workers under the slogan, "Everyone changes, and everyone makes changes." Materials management was identified as an issue, and the plant has launched a 5S (*seiri* [tidiness], *seiton* [orderliness], *seiso* [cleaning], *seiketsu* [cleanliness], and *shitsuke* [discipline]) promotion team, inculcated the practice of "Have nothing unnecessary," and rethought its plant-wide rules for review and retention of stored items.

Although each individual operational improvement is small, the team members are encouraged by employee feedback such as "My work is easier" and "It's easy to find what I need."

Going forward, we will continue to foster a culture in which employees voluntarily work on improvement.

The Kurihama Plant's 5S activities promotion team

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 300 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 and that assure sterility of the products.

* 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.

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 230 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.

MARKETING

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's activities such as sales strategy planning, market analysis, collaborations with academic societies, and product information materials creation are conducted in close cooperation with these partners for promoting market penetration.

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, from glass to plastic. Through these efforts, we are adding value to our products.

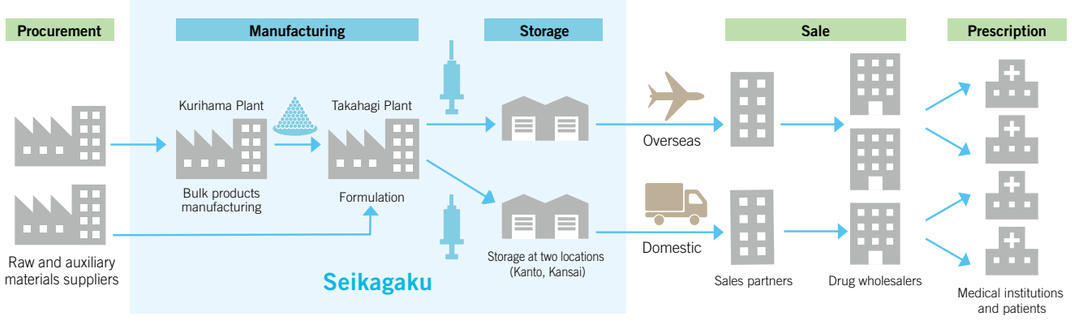
To accelerate and expand our overseas business, Seikagaku is committed to continuously grow in its current markets, and also develop new markets, by responding to global medical needs with its products.

Bulk products

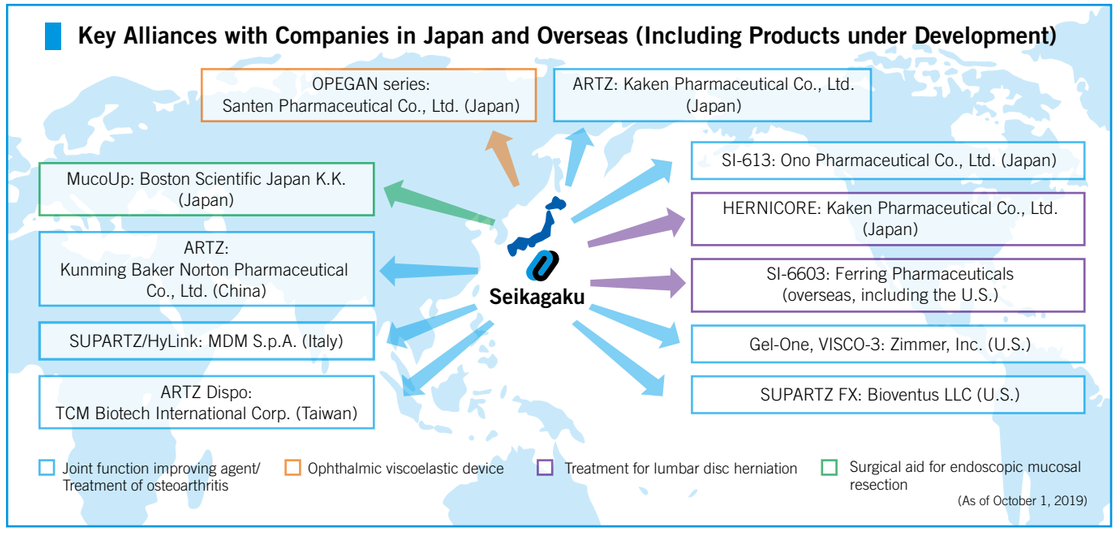
Seikagaku's business can be traced back to 1950 when it became the first company in the world to successfully produce chondroitin sulfate on a commercial scale. The key to success was its unique extraction and purification technologies. With these technologies, Seikagaku manufactures high-purity and 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.

Supply Chain for Main Products



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



Endotoxin-detecting reagents (LAL business)

The endotoxin-detecting reagents that Seikagaku provides are mainly used in quality control of pharmaceutical and medical device manufacturing processes and water quality control of dialysate used in artificial dialysis.

Seikagaku is engaged in the development of the LAL business in Japan, selling endotoxin-detecting reagents and related devices mainly to pharmaceutical companies that manufacture injectable formulations, while wholly owned subsidiary Associates of Cape Cod,Inc. (ACC) handles overseas business development. ACC is the first company in the world to successfully develop endotoxin-detecting reagents from limulus amebocyte lysate (LAL), and it obtained U.S. Food and Drug Administration (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®, an intra-articular viscosupplement for the treatment of knee osteoarthritis, in Italy

In March 2019, Seikagaku launched HyLink in Italy as medical device through its sales partner MDM S.p.A.. HyLink is an intra-articular single-injection viscosupplement for the treatment of knee osteoarthritis, which contains cross-linked hyaluronate hydrogel as its main ingredient. With its high-viscosity, cross-linked hyaluronate hydrogel has a long-term residual presence in the knee joint cavity, and a single injection with only 3 mL provides pain relief for 26 weeks. The launch of HyLink was announced at Congresso Roma 2019, through a commemorative lecture presentation for local physicians. The inventors from Seikagaku were invited to speak about their success stories and product features.

Seikagaku will continue to support MDM's activities by providing academic information.

HyLink®

180 attendees at Congresso Roma 2019

QUALITY COMPLIANCE

Seikagaku's mission is to provide society with a continuous supply of 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 Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("PMD Act") and 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.

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, according to our Quality Policy, we have developed a quality management system that ensures the reliability of our products worldwide. At the development stage, we ensure reliability under Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). To guarantee quality assurance in accordance with legal and regulatory requirements after product launch, each year we systematically conduct self-inspections and internal audits to confirm the status of operation of the quality management system and promptly take corrective and preventive actions as necessary.

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

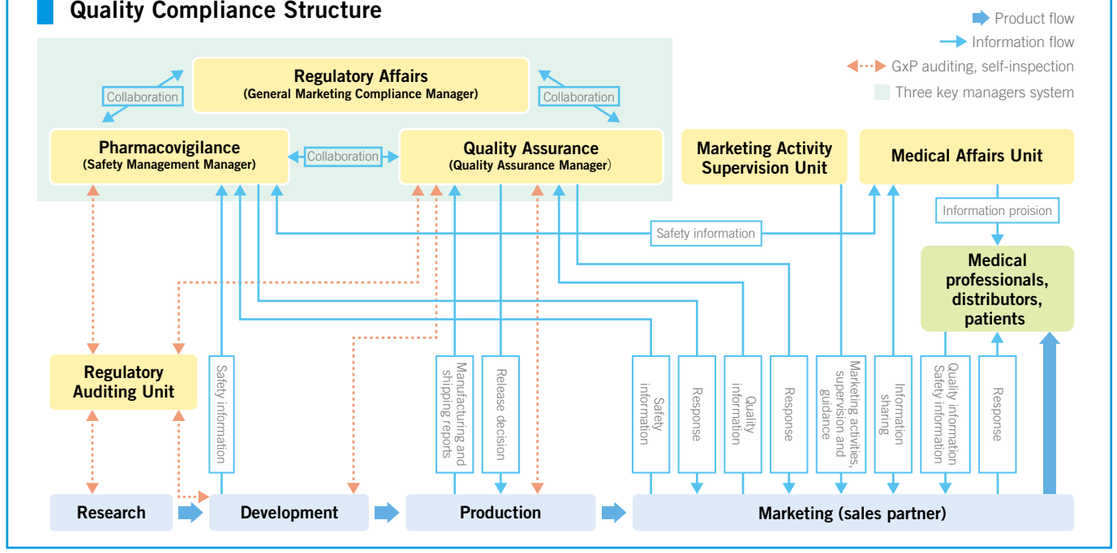
ISO 13485 is an international standard for quality management systems established by the International Organization for Standardization (ISO) that prescribes requirements concerning the design, development, and manufacturing of medical devices. In Japan, ISO 13485 has been adopted as an ordinance on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

Laws and Regulations Governing Pharmaceuticals and Medical Devices

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

- PMD (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

Quality Compliance Structure



Safety management

Sometimes side effects not observed in the development stage come to light after the launch of a new drug. 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 drugs 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 MSL 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

Post-marketing surveillance for further development of HERNICORE®

A year has passed since the launch in August 2018 of HERNICORE, a treatment for lumbar disc herniation, and administration of HERNICORE to patients is steadily increasing. Since the launch, Seikagaku, together with sales partner Kaken Pharmaceutical Co., Ltd., has been focusing on surveying and examining safety, efficacy, and factors affecting them after administration of HERNICORE in medical institutions.

This is a large-scale, long-term surveillance project involving observation of some 3,000 patients for three years after administration. For this reason, we have obtained the cooperation of physicians and patients, developed a framework for close collaboration with Kaken Pharmaceutical, and are steadily working to increase enrollments.

By feeding back the safety and efficacy information obtained through surveillance to medical institutions, we will promote appropriate use of HERNICORE and contribute to post-marketing drug development.

A safety information meeting

HUMAN RESOURCES

Seikagaku aims to develop self-driven and self-disciplined employees who can contribute to sustainable 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 of individuals through a combination of systematic education in various training programs, personnel training in the workplace through day-to-day work, and job rotation.

In addition, to develop the human resources required by each division and department, we conduct age-specific and level-specific training for everyone from rank-and-file employees to executives.

Work-life balance

To help its employees achieve a good work-life balance, Seikagaku has introduced flex-time at all of its business sites except for a few production operations and established a weekly “no overtime day” to encourage employees to leave work at the normal finishing time. To help employees balance the demands of their personal lives with their work activities, Seikagaku encourages employees to develop their own workstyles. For example, we are introducing a reduced working hours system to help employees to take care of childcare and nursing care duties, and there is also a system that allows employees to accumulate lapsed annual paid leave for use during prolonged illnesses or to cope with extended childcare and nursing care responsibilities. In the fiscal year ended March 2019 (fiscal 2018), employees used an average of 79.4% of their paid leave. In the period from fiscal 2007 to fiscal 2018, 100% of staff who left work for childcare reasons returned to work. The number of male employees taking childcare leave has also increased in recent years.

Seikagaku will continue to consider systems to meet workstyle needs as part of its efforts to improve working environments.

Promoting advancement of women

Seikagaku is creating an environment and developing systems 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.

Since April 2016, we have implemented an action plan for the advancement of women, launched an in-house project with the objective of achieving a ratio of female managers of 10% by March 31, 2019, and engaged in various promotion activities spearheaded by female employees and the Human Resources Department. In this project, we have studied improvements to our internal systems based on the results of interviews with all female employees and held workshops to foster a culture that supports advancement of women. As a result of these initiatives, the ratio of female managers was 11.8% as of March 31, 2019, exceeding the target set when the project was launched. Seikagaku will continue to engage in initiatives to promote the advancement of female employees in the workplace.

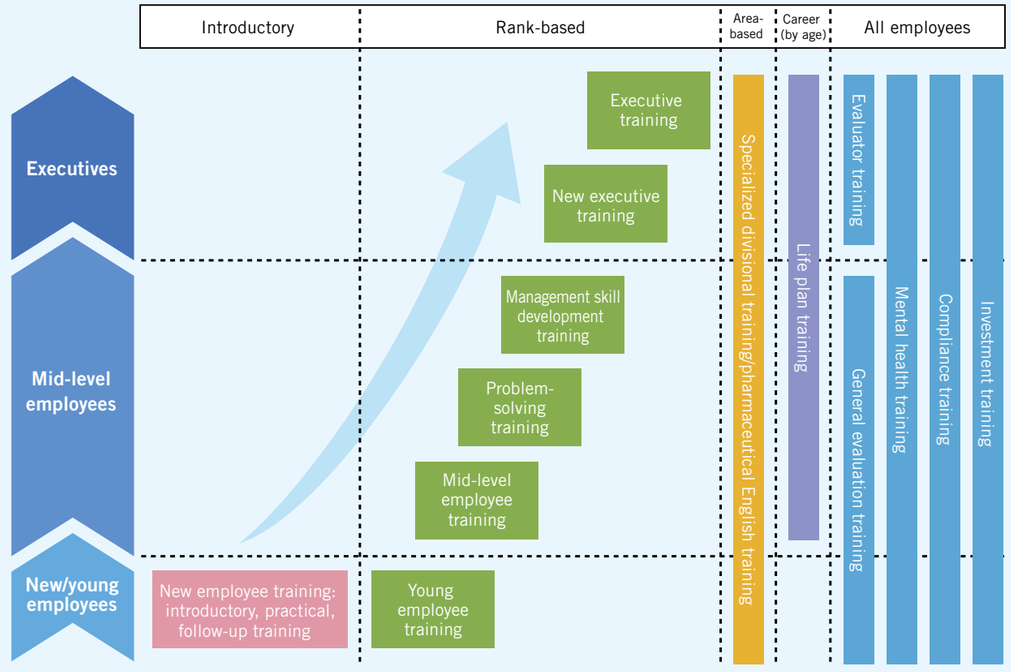
Health and Safety Committees

Seikagaku has formed Health and Safety Committees for the purpose of preventing occupational injuries and maintaining and promoting an appropriate working environment. The Committees meet once monthly at each business site with an industrial physician and public health nurse in attendance to survey the workplace environment and discuss issues. Through the Committees' activities, Seikagaku reinforces initiatives to prevent employee health problems and maintain and promote employee health and is developing a system for obtaining guidance and advice necessary for health management with professional input from an industrial physician and public health nurse.

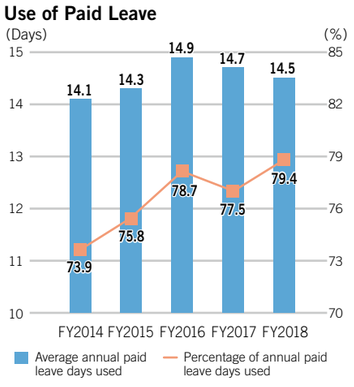
Mental health care (stress checks)

Since 2009, Seikagaku has implemented measures aimed at preventing employee mental illness. Specifically, we periodically aggregate and analyze employee stress values (organizational diagnosis) and, at departments and divisions where stress is high, link the results to personnel allocation corresponding to the nature and amount of work, improvement of the workplace environment, correction of long working hours, and creation of employee-friendly workplaces. We have also instituted an external hotline and counseling service and are developing a framework to enable employees and family members to seek consultation about work-related or personal concerns without hesitation.

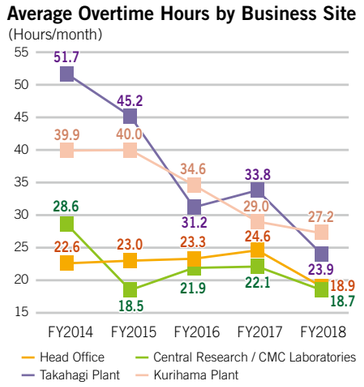
Training Systems



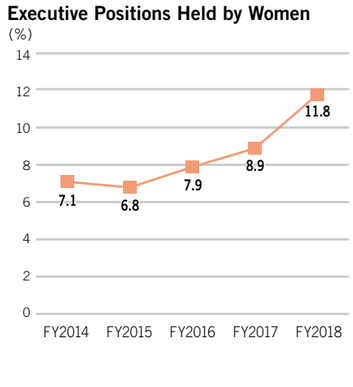
Use of Paid Leave



Average Overtime Hours by Business Site



Executive Positions Held by Women



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

CORPORATE GOVERNANCE

Members of the Board (as of October 1, 2019)

President & CEO *
Ken Mizutani
Term of office as Director:
29 years
Number of the Company's shares owned:
437,316 shares

Executive Vice President
Business Development & Marketing
Toshiyuki Okada
Term of office as Director:
2 years
Number of the Company's shares owned:
4,600 shares

Executive Vice President
Research & Development
Yosuke Funakoshi
Term of office as Director:
1 year
Number of the Company's shares owned:
5,100 shares

Executive Vice President
Corporate Strategy, HR, F&A and Corporate Staff
Takayuki Akita
Term of office as Director:
1 year
Number of the Company's shares owned:
1,800 shares

Outside Member of the Board
Eiji Katayama
Term of office as Director:
15 years
Number of the Company's shares owned:
36,100 shares

Outside Member of the Board
Mio Minaki
Term of office as Director:
—
Number of the Company's shares owned:
—

Audit & Supervisory Board Member
Toru Takeda
Term of office as Audit & Supervisory Board Member:
3 year
Number of the Company's shares owned:
1,900 shares

Audit & Supervisory Board Member
Shigeru Kawahara
Term of office as Audit & Supervisory Board Member:
2 years
Number of the Company's shares owned:
5,000 shares

Outside Audit & Supervisory Board Member
Yoshihito Shibata
Term of office as Audit & Supervisory Board Member:
4 years
Number of the Company's shares owned:
1,300 shares

Outside Audit & Supervisory Board Member
Mie Fujimoto
Term of office as Audit & Supervisory Board Member:
4 years
Number of the Company's shares owned:
1,300 shares

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

Head of Corporate Staff
Executive Vice President
Mikako Torii

Quality Compliance
Executive Vice President
Yuji Shimojima

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

*Ken Mizutani concurrently serves as an executive officer.
Notes: 1. Terms of office are as of June 19, 2019.
2. Number of the Company's shares owned is as of March 31, 2019.

Basic policy of corporate governance

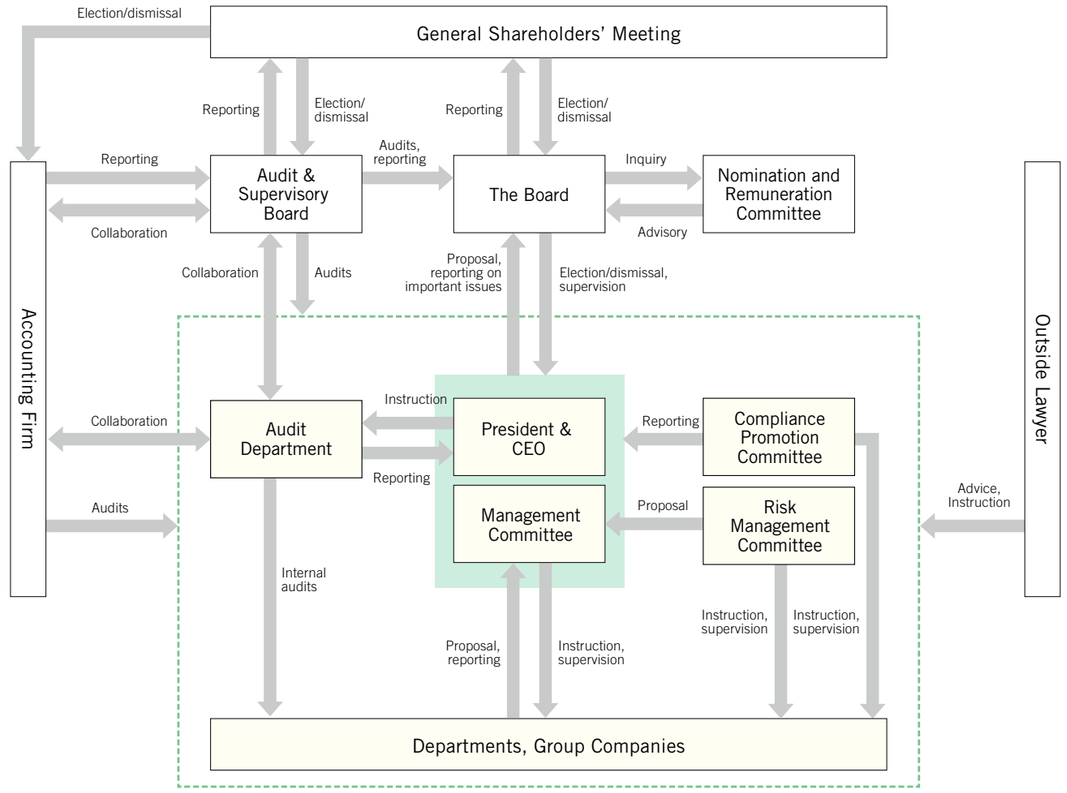
Seikagaku Corporation views corporate governance as a core area of management priority, and endeavors to gather information accurately and adequately, speed up decision-making, and strengthen the supervisory function of business execution. We are profoundly aware of our social mission and responsibilities 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.

Concrete approach and measures for corporate governance

The Board

- The Board holds regular monthly meetings to make decisions on tasks stipulated in laws, the Articles of Incorporation and rules for the Board, such as basic management policy, mid-term management plan, annual management plan, and election of executive vice presidents. The Board decides on important business, and supervises the performance of business operations. If necessary, additional meetings of the Board are convened.
- 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 Board comprises four full-time and two outside members. We enhance management oversight from an independent standpoint by appointing outside members of the Board to one-third of the Board seats.

Corporate Governance Structure



- 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.
- All two outside members of the Board are reported to the Tokyo Stock Exchange, Inc. as independent officers.
- The documents and supplemental materials on the agenda are generally distributed to the members three days before the date of the Board meetings in order to ensure review time for ample discussions.
- The Board consults with the Nomination and Remuneration Committee, which consists of the President & CEO and all outside members of the Board, in determining matters concerning compensation and candidates for members of the Board, and makes decisions based on the advice received.
- Outside officers meetings, comprising the outside members of the Board and outside Audit & Supervisory Board members, analyze and evaluate the effectiveness of the Board periodically. After reporting the results to the Board, the secretariat works to improve the management of the Board.

Audit framework

- The Audit & Supervisory Board comprises five members, two full-time and three outside members, and each member audits the Board members' execution of duties.
- Out of five members, each one of full-time members and outside members have enough knowledge of finance and accounting.
- 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.
- To strengthen the oversight function, Audit & Supervisory Board members attend the Board, and the full-time Audit & Supervisory Board members attend important meetings of the Management Committee, Compliance Promotion Committee, Risk Management Committee, and other management bodies and receive reports concerning the status of management and business execution.
- The Audit & Supervisory Board increases audit effectiveness and efficiency by holding regular meetings with the President & CEO and the Audit Department, and by interviewing members of the Board in charge and heads of each department according to an annual program.
- The Audit & Supervisory Board members hear from the accounting auditors about the annual audit plan of the accounting auditor and the results of the accounting audit, etc. and exchange views.

Business operations

- Seikagaku operates an executive vice president system for enhancing the corporate governance. Under this system, executive functions are separated from the Board, the functions of which are limited to decision-making and the supervision of business operations. Seikagaku endeavors to build up an internal system, which is quickly able to respond to changes in the management environment, by improving the flexibility and efficiency of executive functions, expanding the executive vice president system, and promoting the transfer of authority.
- Seikagaku holds weekly Management Committee meetings. The Committee, composed of full-time members of the Board and executive vice presidents, confers and decides agendas of executive functions they have been tasked for implementation by the Board, based on the basic policy of the Board.

Compliance/risk management

- In addition to the social ethics code, in order to comply with strict laws and regulations of the pharmaceutical industry, Seikagaku has established a compliance program (including the SKK Group Compliance Code of Conduct) based on the Creed and the Guidelines for Our Activities as defined in our Core Values. The Seikagaku Compliance Program Handbook is compiled and distributed to increase the awareness and understanding of employees.
- The Compliance Committee is chaired by the President & CEO and shares the same members as the Management Committee. There are also various programs to promote compliance on a company-wide basis. And Seikagaku has implemented various measures to enhance effectiveness.
- To appropriately manage business risks and take risk prevention measures, Seikagaku has established a Risk Management Committee, chaired by a Board member in charge of administration and comprising the executive vice presidents in charge of various departments.
- Seikagaku controls subsidiaries adequately by stipulating the rules for regularly reporting important events, such as compliance and risk status, in addition to financial condition, ensuring adequate and efficient operation of subsidiaries.
- Seikagaku ensures that management decision and daily business execution are in compliance with laws and regulations by receiving advice and instructions from outside lawyers.

Accounting audit and Internal audit frame work

- Seikagaku has selected Deloitte Touche Tohmatsu LLC as the accounting auditor following comprehensive evaluation of its auditing accomplishments, independence, quality control system, and other factors.
- The Corporate Audit Department, consisting of three employees, conducts audits for the purpose of assessing and verifying the legality and appropriateness of the Seikagaku Group's operations.

Coordination between Audit & Supervisory Board members, accounting auditors, and internal audits

- The Audit & Supervisory Board members and the Corporate Audit Department met 25 times during fiscal 2018 to review audit results related to internal controls at each internal division, and share information and views on the audit plan and the status of audits conducted by the Corporate Audit Department. They also aim to reach a mutual understanding through spontaneous communications.
- Regarding the state of coordination between the Audit & Supervisory Board members and the accounting auditors, information exchange was provided for on 11 occasions during fiscal 2018, and the year's plan for the auditing firm and the results of the financial audit were received at a hearing where views on these matters were also exchanged.
- The Corporate Audit Department cooperates with the accounting auditors to share information and exchange views on audit plans concerning internal controls, audit implementation status and audit results for ensuring the reliability of the Company's financial reports.

Outside members of the Board and outside Audit & Supervisory Board members

Number of outside members of the Board and outside Audit & Supervisory Board members

- The Company has two outside members of the Board and three outside Audit & Supervisory Board members. All five outside officers satisfy the conditions for independent directors or auditors stipulated by the Tokyo Stock Exchange, Inc. and the Company's Independence Criteria for Outside Officers. The Company has submitted notification to the Tokyo Stock Exchange that all five outside officers are independent officers.

Interests including those having a personal relationship, capital relationship, or transactional or other business relationship with the Company

- Concerning relationships between our company and another company in which the same person serves, or has served, as an outside member of the Board or an outside Audit & Supervisory Board member, there are no interests that would be affected by a personal relationship, a capital relationship (except for the holding of our company stock through a compensation system linked to the stock price), a business relationship, or performance of other work duties.
- Under the approval of the 73rd Ordinary General Meeting of Shareholders held on June 19, 2019, the Company has introduced a restricted stock compensation system as part of officer compensation. As a result, the stock price-linked compensation system has been abolished. Outside directors and outside corporate auditors are not subject to the restricted stock compensation system.

Functions and roles carried out in corporate governance

- The outside members of the Board oversee management and contribute to strengthening of the Company's corporate governance system by providing advice and recommendations from an objective standpoint, which is based on expert knowledge and insights into corporate management and incorporates the common interests of shareholders.
- The outside Audit & Supervisory Board members appropriately fulfill their role of overseeing the execution of duties by Board members by striving to gather information and expressing their views from an objective standpoint, which is based on expert knowledge and insights into corporate management and incorporates the common interests of shareholders.

Standards and guidelines of appointment with respect to the independence from the Company for the appointment, and approach concerning appointment status

- The Company stipulates that in order to fulfill the criteria for independence, an outside officer must not fall under any of the following:

A. A person who executes business of the Company and its group companies (the "Group").
B. A party who provides the Group with products or services whose transactions with the Group accounted for at least 2% of their consolidated net sales in the most recent fiscal year, or a person who executes business thereof.
C. A party to whom the Group provides products or services whose transactions with the Group accounted for at least 2% of the Company's consolidated net sales in the most recent fiscal year, or a person who executes business thereof.
D. A consultant, an accounting expert, or a legal expert who received ¥10 million or more of monetary consideration or other property from the Group in the most recent fiscal year (or if the entity receiving such property is an organization, such as a corporation or an association, a person belonging to such entity which received at least 2% of its total annual income from the Group).
E. A party who received donations of ¥10 million or more from the Group in the most recent fiscal year, or a person who executes business thereof.
F. A shareholder who held at least 10% of the total voting rights of the Company at the end of the most recent fiscal year, or a person who executes business thereof.
G. A person who fell under any of the above criteria (A) to (F) within the past three years.
H. A relative who is within the second degree of kinship or who is living together with a person falling under any of items (A) to (G) above.
I. A party who is deemed to have any other significant interest in the Group, or a person who executes business thereof.

- From the candidates for outside member of the Board, we select well-qualified persons who apply insight from specialized expertise and corporate management and who can exercise appropriate supervision of business execution from an objective standpoint, including a viewpoint of shared profits with shareholders. From the candidates for outside Audit & Supervisory Board member, we select well-qualified persons who apply insight from specialized expertise and corporate management and who can exercise appropriate supervision of the Board's performance of duties from an objective standpoint, including a viewpoint of shared profits with shareholders.
- Because they fulfill the standards of independence for outside officers set by the Company and the standards of independent officers set by the Tokyo Stock Exchange, Inc. and we believe that the outside members of the Board and the outside Audit & Supervisory Board members hold sufficient independence from the management that executes the Company's business.

Compensation for corporate officers

Basic policy on compensation for corporate officers

The Company's basic policy on compensation for corporate officers is to contribute to sustained earnings improvement by increasing incentives for corporate officers to meet the expectations of shareholders.

Compensation for corporate officers consists of basic compensation that reflects consideration of the balance between the going rate, management performance, and employee salaries and, for directors other than outside directors, earnings-linked compensation and performance-linked compensation, which serve as short-term incentives, and restricted stock compensation, which serves as a long-term incentive.

Earnings-linked compensation, a short-term incentive, is calculated using the level of profits in the previous fiscal year. Performance-linked compensation is determined in accordance with qualitative assessment of achievement of objectives by each director in the previous fiscal year.

Restricted stock compensation, a long-term incentive, involves the granting each year of common shares of the Company for which transfer is restricted until retirement. The purpose is to provide an incentive for directors (excluding outside directors) to pursue sustained enhancement of the Company's corporate value and promote further sharing of value with the shareholders by promoting long-term, stable shareholding. Compensation for outside directors and Audit & Supervisory Board consists of basic compensation only, in view of their management oversight role.

Method of determining compensation for corporate officers

The amount of compensation for corporate officers is determined in accordance with the above basic policy within the maximum amount approved by the General Shareholders' Meeting, with the amount for directors determined by the Board of Directors and the amount for Audit & Supervisory Board members determined by discussion among them. When determining compensation for directors, the Board of Directors consults with the Nomination and Remuneration Committee, comprising the president and CEO and all of the outside directors, and deliberates in light of the consultation results.

Total amount of compensation for each category of officer, total amount by type of compensation, and the number of relevant officers (fiscal year ended March 2019)

Officer category	Total compensation (Millions of yen)	Total by type of compensation (Millions of yen)			Number of officers
		Basic compensation	Earnings-linked compensation	Other	
Members of the Board*	230	204	25	—	6
Audit & Supervisory Board members*	45	45	—	—	2
Outside officers	47	47	—	—	5
Total	323	297	25	—	13

*Excluding outside officers

Notes: 1. Based on the status at the time of adjournment of the 72nd Ordinary General Shareholders' Meeting held on June 20, 2018, two retired member of the Board are included in the table above.
2. The amount of pay for a member of the Board does not include the employee portion of salary of someone who is concurrently an employee and a member of the Board.
3. 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 Board member proportion shall be no more than ¥50 million per year).
4. 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.
5. Regarding the remuneration of directors (excluding outside directors), at the 73rd Ordinary General Meeting of Shareholders held on June 19, 2019, we were approved the introduction of a restricted stock compensation system with a transfer limit of no more than ¥50 million per year. The total number of the Company's common stock shares issued or disposed for the grant of restricted stock shall be 40,000 or less per year.

Main activities of the outside members of the Board and the outside Audit & Supervisory Board members (fiscal year ended March 2019)

Officer category	Last/First name	Independent officer	Board meetings	Audit & Supervisory Board meetings
Outside member of the Board	Eiji Katayama	○	Attended 13 of 13 meetings	—
	Izumi Hayashi	○	Attended 13 of 13 meetings	—
Outside Audit & Supervisory Board members	Nobuhiro Takeuchi	○	Attended 12 of 13 meetings	Attended 13 of 14 meetings
	Yoshihito Shibata	○	Attended 13 of 13 meetings	Attended 14 of 14 meetings
	Mie Fujimoto	○	Attended 13 of 13 meetings	Attended 14 of 14 meetings

Compliance promotion activities

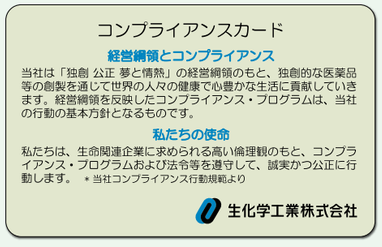
In order to ensure a strong sense of ethics across all of its corporate activities, Seikagaku Corporation strives as a pharmaceuticals company, not simply to comply with relevant laws and regulations, but also "to regulate its own conduct in accordance with a moral understanding (proper thinking on what human beings ought to do intrinsically) and to have the courage to rectify the misdeeds of others," positioning sincere and fair conduct this as a basis of all activities.

To embody these principles, we have established a Compliance Program that, among other things, has promulgated a Code of Conduct for the Group. In addition, in order for the program to proceed better in an appropriate manner and without obstruction, we have established a Compliance Promotion Committee and develop an annual action plan. Through these actions, we promote greater compliance awareness on an all-company scale and increase its effectiveness.

We have also distributed to all employees and publicized a Compliance Program Handbook that describes the contents of this program and a Compliance Card that summarizes the key points of conduct

In the fiscal year ended March 31, 2019 (fiscal 2018), we instituted an activities policy of strengthening the compliance promotion system through understanding of matters that must be complied with in business activities and a sense of ownership on the part of officers and employees. We worked to ensure compliance effectiveness by developing internal systems and undertaking sufficient internal penetration of compliance awareness through training, mainly for the purpose of complying with revisions to laws, ordinances, and regulations relating to the Company's business operations.

We have also set up multiple contact points for consultation, including an outside attorney, and have put in place a system to promote the prompt discovery and early resolution of problems. There were six consultations in the fiscal 2018, all of which were handled appropriately.



Compliance Card

BUSINESS RISKS

The following are the principle risks that could have a material effect on the operating results and the financial situation of Seikagaku Corporation.

Legal restrictions, healthcare system and administrative trends

Many of the Seikagaku's products affect people's lives and health and, consequently, are subject to legal restrictions for ensuring the quality, efficacy, and safety of pharmaceuticals and other products imposed by regulatory authorities in Japan and other countries. Amendments to these related laws and regulations or healthcare system and administrative policy trends, including revisions to the National Health Insurance Drug Price Standard, could affect our business results.

Timeframe and expense required for new product development

In pharmaceutical product development, the core of Seikagaku's business, various clinical studies to confirm efficacy and safety are required from the time of basic research to new drug approval. Even if the Company bears enormous R&D expenses over long periods of time, there is risk that products under development will not progress to launch. R&D expenses vary according to R&D progress, and this could affect our business results.

Reliance on specific distributors

We have entered into exclusive distributorship agreements with sales partners for the pharmaceuticals and medical devices that are our mainstay products, which limits the number of distributors. Changes to the business relationships with these companies due to changes in circumstances, depending on the nature of the changes, could affect our business results.

Reliance on specific products

Joint function improving agents and ophthalmic viscoelastic devices account for a majority of the net sales of the Pharmaceuticals business in Japan and overseas markets in the fiscal year. Consequently, any unforeseen material side effects or other events that have a material effect on the manufacturing and sale of these mainstay products could affect our business results.

Reliance on specific suppliers

Various restrictions apply to the manufacture of pharmaceuticals, and some raw materials require the approval of regulatory authorities. Therefore, the number of raw materials suppliers is limited, and we perform on-site audits and strive to maintain quality and establish a stable supply system. We rely on single supply sources for certain raw materials. Consequently, any change in circumstances that makes it difficult to procure raw materials could disrupt the manufacture of products and affect our business results.

Use of animal-derived ingredients as raw materials

Many of the Seikagaku's products are made using ingredients derived from animals, namely chickens, sharks, and horseshoe crabs, as raw materials. Consequently, any restrictions on the use of animal-derived ingredients as raw materials or difficulty in procuring these ingredients could affect our business results.

Exchange rate fluctuations

Our export transactions are denominated mainly in U.S. dollars. Although we endeavor to reduce exchange risks by denominating a portion of R&D expense payments in foreign currencies and entering into foreign exchange contracts, exchange rate trends could affect our business results.

Price fluctuations of holdings of marketable securities

We invest cash reserves in marketable securities for the purpose of applying them to future R&D and capital expenditures. Although we endeavor to reduce risks through diversification of investments and other means, price fluctuations of marketable securities and other investments could affect our business results.

Litigation

Initiation of litigation relating to pharmaceutical side effects, product liability, patents or other intellectual rights, labor problems, depending on the details, could affect our business results.

Occurrence of large-scale disasters

Any stagnation of business activities or disruption of product supply as a result of extensive damage to the Seikagaku Group's business sites due to an earthquake, a typhoon or other natural disaster, fire or other accident, or an epidemic of a new influenza virus or other infectious disease could affect our business results. Also, any major expenses for the repair of facilities damaged in a disaster could affect our business results.

Status of development and operation of risk management regulations and systems

Regulations and other systems related to the management of risk of losses

- We have established business risk management regulations and developed a system to ascertain and manage risks pertaining to business execution.
- We have established the Risk Management Committee, chaired by the chief risk management officer (the member of the Board in charge of Corporate Strategy, Human Resources, Finance and Accounting, and Corporate Staff) and comprising the executive vice presidents in charge of various departments. The Committee deliberates risk prevention measures and, when a material business risk event occurs, establishes a response headquarters and takes measures to minimize damage.

Status of operation of risk management systems

The Risk Management Committee met in the fiscal year ended March 31, 2019 and deliberated major issues such as strengthening of the confidential information management system, confirmed the status of progress with group-wide risk prevention measures, and sought to prevent risk events from occurring.

In addition, we strove to reduce risks relating to our business by renewal of accident procedure manuals for the purpose of increasing the effectiveness of the rapid business recovery response, and developing systems to promote appropriate disposal of documents whose retention deadlines have passed.

SOCIAL CONTRIBUTION ACTIVITIES

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

Plant tours for learning about and experiencing manufacturing

Every year since 2012, Seikagaku Corporation has conducted tours of the Takahagi Plant for elementary school students to give children the opportunity to experience a manufacturing site up close. These tours enable students to learn about pharmaceutical manufacturing through observation of the formulation process and familiarize them with initiatives for quality control necessary for the manufacturing and stable supply of high-quality pharmaceuticals. During the tours, we also aim to stimulate interest in chemistry and experimentation by providing hands-on experience of a simple cider-making process using familiar everyday articles.

Through such interaction with host community residents, we support the development of the children who will become tomorrow's leaders.

Children eagerly answer quiz questions

Experiencing the viscosity of hyaluronic acid

Horseshoe crab conservation activities

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.

ACC has long engaged in an activity to collect and fertilize horseshoe crab eggs *in vitro*, grow them into survivable crabs, and release them into the natural environment, accumulating experience in aquaculture systems and species-specific culture expertise in this process. This assistance will be made available to academic institutions and private sector researchers around the world, starting with organizations in China and Malaysia. Organizations receiving assistance will be granted a license to use ACC proprietary technology and expertise free of charge, and they are provided customized tools, instruction in *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 exceeded 250,000 in 2019. The Seikagaku Group will continue to promote activities to conserve and sustain horseshoe crab populations worldwide, and strive to use this precious resource in a sustainable, responsible manner.

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

Released American horseshoe crabs

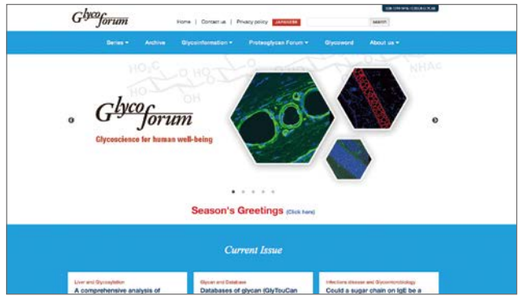
Seikagaku pursues respect for learning by engaging in global research assistance and sponsoring activities that support the development of glycoscience.

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, and was selected as one of the recommended websites by the worldwide scientific journal *Nature Reviews*.



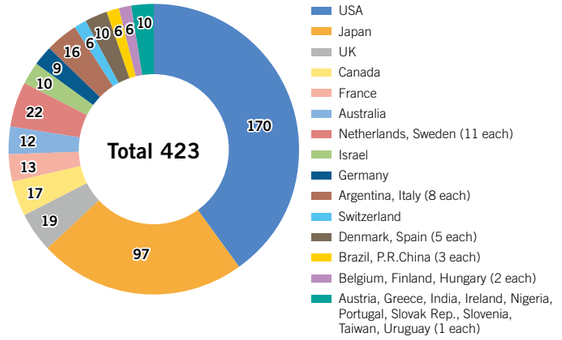
Support for the Mizutani Foundation for Glycoscience

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

The Mizutani Foundation for Glycoscience 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 2018, the Foundation provided research grants totaling approximately ¥72.3 million to 16 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: 1993–2019)



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. Visitors can also download a pamphlet "Exercise therapy of knee osteoarthritis."

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

FINANCIAL / NON-FINANCIAL HIGHLIGHTS

Basic policy on profit distributions

The improvement of shareholder value is an important management priority. Our goal is to enhance shareholder returns while achieving sustainable growth through balanced business investment, including investment in R&D and the improvement of production structures.

Our policy on shareholder returns is to maintain dividend stability from a medium- to long-term perspective by continuing to pay an annual dividend of ¥26 per share. We will also continue to consider share buy-back schemes, while giving due consideration to future business development and the overall payout ratio.

In the year ended March 31, 2019, we set the final dividend at ¥13 per share. Together with the interim dividend of ¥13 per share, this resulted in an annual dividend of ¥26 per share for the year ended March 31, 2019, equivalent to a payout ratio of 65.4%.

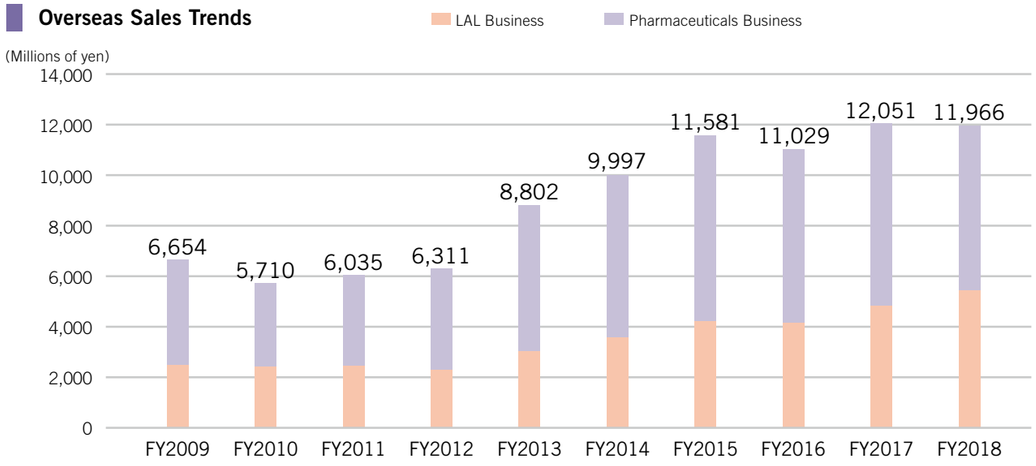
Consolidated Business Performance

(Millions of yen)

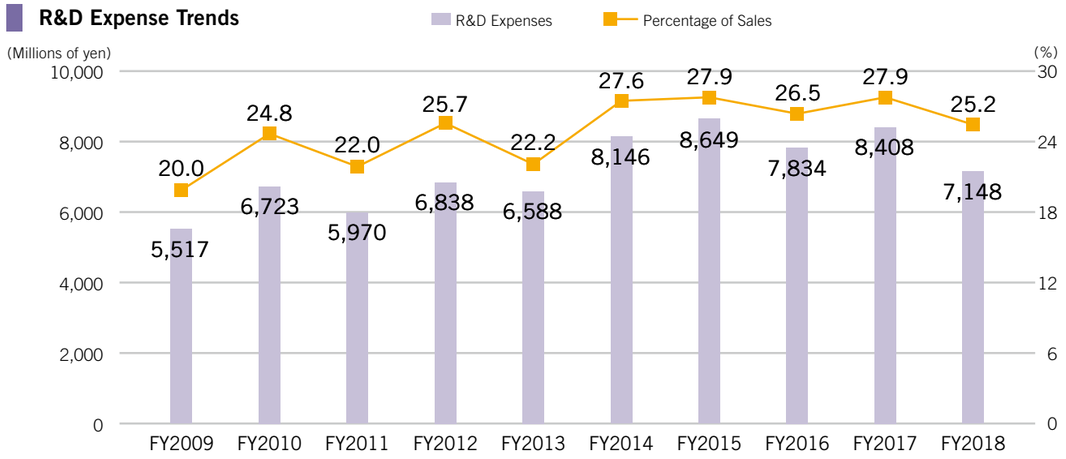
	FY2014	FY2015	FY2016	FY2017	FY2018
Net Sales	29,522	30,962	29,589	30,175	28,384
Overseas Sales	9,997	11,581	11,029	12,051	11,966
Overseas Sales Ratio (%)	33.9	37.4	37.3	39.9	42.2
Cost of Sales	12,130	12,871	13,247	13,008	13,114
Gross Profits	17,391	18,091	16,341	17,166	15,270
R&D Expenses	8,146	8,649	7,834	8,408	7,148
Operating Income	2,383	2,144	1,282	1,421	977
Operating Income Ratio (%)	8.1	6.9	4.3	4.7	3.4
Ordinary Income	4,008	3,500	2,477	5,327	2,859
Net Income	3,650	2,578	1,787	3,922	2,244
Net Income Ratio (%)	12.4	8.3	6.0	13.0	7.9
Total Equity	70,410	69,815	70,646	73,945	73,036
Return on Equity (ROE) (%)*1	5.4	3.7	2.5	5.4	3.1
Total Assets	80,889	80,218	80,048	84,749	80,238
Return on Assets (ROA) (%)*1	5.2	4.3	3.1	6.5	3.5
Dividend Payout Ratio (%)	40.5	57.3	98.3	37.5	65.4
Net Income per Share (yen)	64.27	45.39	31.55	69.30	39.76
Total Equity per Share (yen)	1,239.51	1,229.05	1,248.07	1,306.37	1,294.88
Dividends per Share (yen)	26.00	26.00	31.00*2	26.00	26.00
Number of Employees (persons)	649	663	687	718	744

*1 Total Equity and Total Assets are average amounts of the numbers for the end of previous fiscal year and the end of current fiscal year, respectively.
*2 Including a 70th anniversary commemorative dividend of 5 yen per share.

Overseas Sales Trends

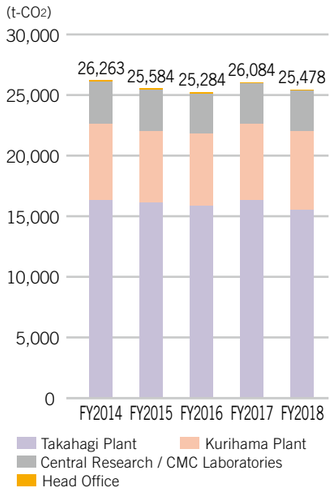


R&D Expense Trends

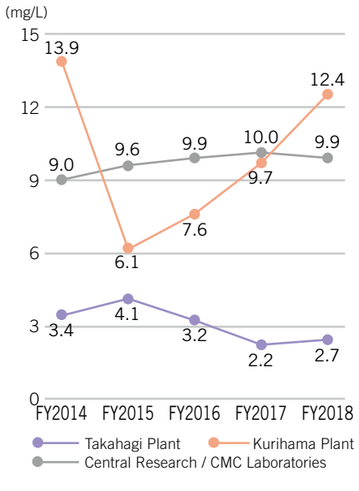


Non-financial Highlights (Non-consolidated Basis)

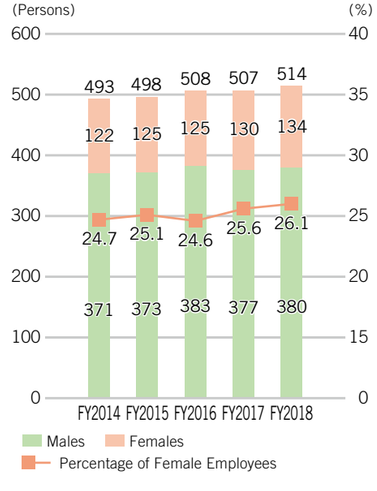
CO_2 Emissions



Water Pollution Load (COD)



Composition of Work Force

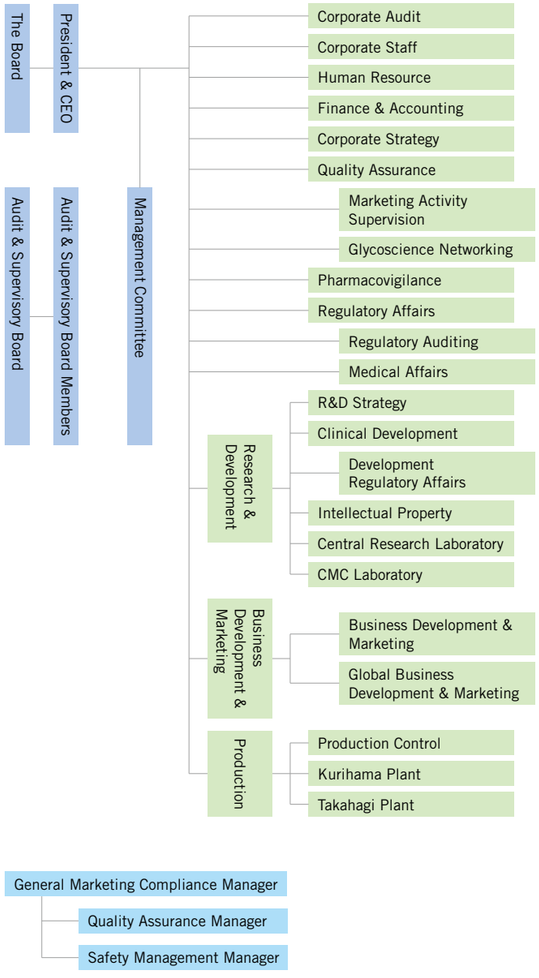


CORPORATE DATA

Overview

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	744 (Consolidated) (As of March 31, 2019)
Paid-in Capital	¥3,840 million (As of March 31, 2019)
Net Sales	¥28,384 million (As of March 31, 2019)

Organization Chart (As of October 1, 2019)



Locations

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

Major Subsidiary

ASSOCIATES OF CAPE COD, INC.

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

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

STOCK INFORMATION

Stock Information (As of March 31, 2019)

Shares per Unit	100
Authorized Shares	234,000,000
Authorized Outstanding Shares	56,814,093
Number of Shareholders	10,295
General Shareholders' Meeting	June
Date of Record for Shareholders Eligible to Receive Dividends	March 31

Shareholder Registry Administrator

Mitsubishi UFJ Trust and Banking Corporation

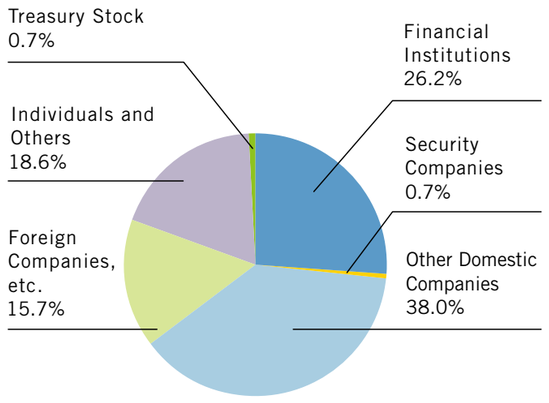
《Contact》
Mitsubishi UFJ Trust and Banking Corporation
Securities Agency Division
PO Box 29, New Tokyo Post Office,Tokyo 137-8081
Tel: 0120-232-711(Domestic toll-free)

Major Shareholders (As of March 31, 2019)

	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)	3,118	5.5
4	Japan Trustee Services Bank, Ltd. (Trust account 9)	2,043	3.6
5	Trust & Custody Services Bank, Ltd. as Trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co, Ltd.	1,973	3.5
6	MUFG Bank, Ltd.	1,536	2.7
7	Japan Trustee Services Bank, Ltd. (Trust account)	1,218	2.2
8	Kaken Pharmaceutical Co., Ltd.	1,207	2.1
9	The Bank of New York Mellon (International) Limited 131800	1,201	2.1
10	State Street Bank and Trust Company 505001	941	1.7

※Treasury stock (410 thousand shares) is excluded from the calculations of the percentages above.

Breakdown of Shareholders by Type (As of March 31, 2019)



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 represents 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

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