

# Corporate Profile

SEKISUI MEDICAL CO., LTD. Confidence Inspired by Quality

SEKISUI MEDICAL CO., LTD.

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# Providing intelligent solutions with science, we contribute to the realization of a healthy and sustainable world.

Sekisui Medical aims to contribute to the realization of a healthy and sustainable world by providing intelligent solutions with science that improve the health of people around the world. Our company was established through the merging of the Medical Products Division of Sekisui Chemical with Daiichi Pure Chemicals in 2008, and has become the core company in Sekisui Chemical's life sciences business. In addition to consolidating and expanding our key diagnostics and pharmaceutical sciences businesses here in Japan, we are accelerating our global business expansion in regions such as North America, Europe and Asia.

In recent years, social and consumer needs for medical care have been diversifying in line with the dramatic transformations of the global medical environment.

Our decades-long legacy of proven expertise and global synergies among our global group companies help us to provide intelligent solutions.

Brand Promise

# Confidence Inspired by Quality

#### Our Vision

#### To create a healthy, sustainable world

Our vision encapsulates what we ultimately hope to achieve through our business. It is a long-term guiding principle for achieving our objectives.

We will realize this vision through our business, which contributes to everyone's health.

#### Our Mission

#### To provide intelligent solutions to enhance life with science and improve the health of all people

This is the mission we must accomplish in order to realize our vision throughout society. It is the very reason for our existence.

#### Our Values

To carry out our mission, we at SEKISUI Medical Group, base our decisions and actions on the following six values.



#### Integrity

We conduct business honorably, ethically, and authentically in all our professional interactions.



#### Quality

Our dedication to quality is our highest priority.

Accuracy, precision, and reliability inspire our customers' confidence in us.



Focus

#### Customer Focus

We listen, anticipate, and address our customers' needs.

We strive for quality and service to build a relationship of trust with our customers



#### Growth

As individuals, we embrace professional growth; as a division,

we pursue diverse opportunities to grow our business and increase its impact on healthcare.



#### Diversity & Inclusion

We value and respect differences among all employees, and promote a trusting, collaborative, and productive working environment that enables us to operate our global workplace with a sense of unity.



#### Creativity & Innovation

We encourage original thinking and value the passion to learn, explore, and improve We create innovative solutions that impact the health of all people.

### Diagnostics Business

We conduct manufacturing and sales for a wide range of analytical equipment including fully-automated blood coagulation analyzers, plastic vacuum blood collection tubes which are essential for clinical analysis, and clinical diagnostic reagents with a focus on blood coagulation, lifestyle diseases, and infectious diseases. The Diagnostics Business Group serves as the core business of our company. We mainly develop, manufacture and market in vitro diagnostics for hospital laboratories and clinical test centers. As a pioneer of biochemical testing, Sekisui Medical has always played a leading role with regard to in vitro diagnostics for the biochemical sector. In particular, the originality of the core technologies we apply in the lipids field keeps us way ahead of our competitors. The reagents we have developed to directly measure HDL-C and LDL-C hold a large amount of shares both in Japan and overseas.



#### **Characteristics of Our Business**

#### Four key areas to meet a wide range of needs

we have also launched a new latex reagent created by combining diagnostics development techniques (LTIA method) with latex technology that is based upon microparticle technology. Our product lineups focus on Four key areas (biochemistry, blood coagulation, diabetes, and infectious diseases), and we aim to win the top market share in each of these sectors. In addition, we are expanding our lineup of specialized analyzers in each key area. We offer a system of diagnostics and analyzers to meet a wide range of customer needs.

#### We have a support system that respond swiftly to customer requests.

Our Customer Support functions as a consultation service to provide support for medical care. We see ourselves as a partner who provides laboratories with reliable information and technologies. We respond to customers' requests via a support system that covers all aspects of testing, and includes technical support to solve any questions you may encounter when you consider using our products, technical and scientific support to ensure trouble-free use, a maintenance service for specialized analyzers, and comprehensive support regarding diagnostics and analyzers. Our maintenance service for specialized analyzers consists of a call center dedicated to dealing with inquiries about equipment and a maintenance office. It has a system in place to respond swiftly to your queries or requests.

#### Our products · Our services

#### Clinical Chemistry, Immunoassay & Diabetes

We offer a full lineup of reagents for use in automated biochemical equipment in various fields, including cancer, rheumatoid arthritis, interstitial lung disease,

and inflammatory bowel diseases, utilizing the latex immunoturbidimetric method as the measurement principle. We also provide reagents for assessing lifestyle-related diseases such as HDLcholesterol and HbA1c.

Coagulation

problems



#### Vacuum blood collection tubes

We offer measurement reagents We offer plastic vacuum blood collection automated analyzers for testing and monitoring coagulation and fibrinolytic accelerant (BCA).



Point of Care Testing (POCT)

We offer easy-to-use rapid test kits and

readers that swiftly indicate test results.

Our lineup of testing reagents is also useful

for making quick decisions on treatment

methods for illnesses such as heart disease,

thrombosis, sepsis, and respiratory infections.

tubes, as well as components such as serum-separating gel and blood clotting



#### Pharmaceutical Sciences Business

The company's three business portfolios — the Pharma & Enzymes Business Department, the Drug Development Solutions Business Department, and the SMCL Center — underpin the foundations of the

We contribute to improving the health and quality of life of all people by providing support for the creation of new medical solutions, such as the manufacture of active pharmaceutical ingredients and pharmaceutical intermediates essential to drug development, the conduct of Preclinical and Clinical Study, the contract testing and the development of tests in collaboration with pharmaceutical companies and medical institutions.



#### **Pharmaceuticals and Enzymes Business**

We contribute to the realization of a healthy and sustainable society by providing high-quality products through contract manufacturing of APIs and intermediates in compliance with GMP.

Our products · Our services

Contract manufacturing services for active pharmaceutical ingredients and pharmaceutical intermediates

In response to requests from pharmaceutical companies, we manufacture active pharmaceutical ingredients (APIs) and intermediates in compliance with GMP for clinical trials and commercial purposes, and supply them globally.



#### BioPharma CDMO

With over 40 year's experience and technology, we provide diagnostic enzyme and biopharmaceutical raw materials to the global diagnostic and pharmaceutical companies.

#### **Drug Development Solutions Business**

We utilize advanced technological capabilities to provide comprehensive support to pharmaceutical companies, academia and institutions involved in drug development.

Our products · Our services

#### Preclinical Study/ Clinical Study

As a contract research organization (CRO), we provide a wide range of services from preclinical to clinical stages to help optimizing the lead compound to submission and post-marketing surveillance of drugs



#### **Products for Preclinical** Researches(Pharmacokinetics and iPS cell culture)

We offer both subcellular fraction and hepatocyte products from many different species to assist your in-vitro ADME researches. We also offer Chemically-Defined Scaffold to culture iPS cells or MSC etc.

#### **SMCL Center**

Based on the philosophy of "creating New clinical value through special clinical laboratory testing and contributing to medical and the company's business", we are actively introducing new assay technologies and new biomarkers. We will provide medical technology to improve the health and quality of life of all people, from newborns to children, including those with growth disorders and dementia.

■ Our products · Our services

#### Child Health Care

As part of Child Health Care, which aims to support healthy growth of the next generation from pregnancy through clinical tests, we propose the contract and sale of expanded newborn screening tests.

Screening for the mild cognitive impairment We measure dementia-related tests



#### Contract testing

We exmaine osteoporosis and rheumatism.

#### Contract resarch

For contract research, it is possible to construct assay systems, measurement validation, measurement of clinical specimens.

### Business foundation for providing safe, secure, high-quality and innovative medical solutions

#### Compliance and Assurance System for Absolute Safety

We are responsible for quality assurance, regulatory affairs, and the quality management system to ensure the compliance with applicable laws and regulations for SEKISUI MEDICAL CO.,LTD's and its group companies' worldwide business.

#### **Quality Assurance Management for All Business Units**

We are responsible for the management of quality assurance systems for all the business units; Diagnostics, Pharmaceuticals and Enzymes, Drug Development Solutions.

#### **Quality Assurance Management at all Global Sites**

We are responsible for the management of quality assurance systems at all global sites located in Japan, North America, Europe and Asia.

#### **Ensuring an Appropriate Response to the Constantly Evolving Business Environment**

We are responsible to ensure that regulatory compliance is adhered to in order to respond appropriately to changes of applicable laws and regulations, international standards and the business environment we work in.

#### North America **Diagnostics Business**

Enzyme Business/Diagnostics Business

#### Asia Diagnostics Business

#### SEKISUI MEDICAL CO., LTD Compliance & Assurance Unit

Compliance & Assurance Department is responsible for quality assurance, regulatory affairs, and the quality management system to ensure the compliance with applicable laws and regulations for SEKISUI MEDICALCO.,LTD's and its group companies' worldwide business.

#### **Diagnostics Business**

We ensure that global operations for our medical devices continue to expand by satisfying registration requirements for each market, including ISO 13485 certification, and the establishment of compliance in line with regulations specified by the authorities, including the FDA.

#### **Pharmaceuticals Business**

We ensure that our high purity pharmaceutical raw materials are globally distributed through the continuous improvement of a GMP system required for active pharmaceutical ingredients (API) and intermediates, and the establishment of regulatory compliance in line with the Japanese Pharmaceutical Authorities and the FDA.

#### **Drug Development Solutions Business**

We ensure that high quality studies are implemented for global customers developing new pharmaceutical products through the continuous improvement of a GLP system required for contracted studies.

In addition, we will maintain a contract manufacturing system and provide high-quality investigational medicinal drugs.

#### Production to continuously provide high-quality products

#### Tsukuba Plant

The Tsukuba Plant is certified in ISO 9001, ISO 13485 and provides high-quality products to our customers. The site has also acquired the ISO 14001 (environmental management system) certification and engages in environmental conservation activities. In addition, we

have achieved ISO 45001 (Occupational Health and Safety Management System) to strengthen our health and



#### Tokvama Plant

The Tokuyama Plant has built a quality management system based on ISO 9001 and ISO 13485 certification and have established a stable supply system by operating an integrated automated production line from raw tube molding to final

product packing of vacuum blood collection tubes. In addition, Sekisui Medical has also produced columns for diabetes testing and components for various medical devices.



#### **Iwate Plant**

The Iwate Plant has established a state-of-the-art GMP system as a manufacturing plant for active pharmaceutical ingredients (APIs) and has maintained its reliability through numerous inspections and audits by the PMDA, the FDA(USA) and other domestic and overseas

pharmaceutical companies, we have also acquired ISO 14001 and ISO 45001 certifications, and are committed to environmental protection and occupational safety.



#### The Drug Development Solutions Center

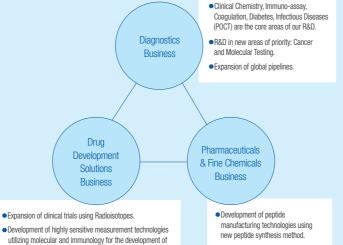
The Drug Development Solutions Center is a research facility located in Tokai-mura, Ibaraki. The Center has undergone GLP compliance survey by the PMDA (Pharmaceuticals and Medical Devices Agency) and is fully

accredited by AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care



#### Research & Development structure to continuously generate new solutions

In order to contribute to the realization of a healthy and sustainable world, we precisely capture current diversified medical needs, and we will continue to create high quality and prominent products through R&D that make full use of our technological capabilities cultivated over many years as well as leverages our core technologies of each R&D site to the fullest through global collaboration.



pharmaceutical products.

Development of concentration measurement technologies

using ultrasensitive techniques to measure nucleic acids.

Research & Development Sites We are establishing a global product pipeline by strengthening the collaboration between our domestic and overseas development sites. This allows us to expand the core segments of each business unit and to develop products that satisfy unmet customer needs.

#### Tsukuba Research Institute

Focusing on the fields of clinical chemistry/immunoassay, coagulation, diabetes and infectious diseases, we conduct R&D of reagents for automated analyzers using enzyme analytical methods and latex immunoturbidimetric methods, as well as

columns for diabetes testing based on separation technology with polymer microparticles, and develop clinical diagnostics products with our proprietary technology.



#### Drug Synthesis R&D Center

We develop manufacturing techniques focused on specialty peptides based on our proprietary peptide synthesis technology.

We also develop manufacturing processes for investigational drugs through the development and implementation of efficient synthesis methods and purification systems for



#### Tsukuba Research Institute, Ami Research Facility

Utilizing our immunoassay, molecular analysis and cell culture technologies, we development for new biomarkers, develop IVD products using highly sensitive immunoassays as well as point-of-care tests in the field of infectious diseases

We develop new evaluation systems and related products for biomarkers, etc. in the non-clinical and clinical fields of

pharmaceutical development through the use of our pioneering immunoassay, molecular analysis and instrumental analysis

### Pharmaceuticals Analysis Group, Tsukuba Research Institute

Time in

#### SEKISUI DIAGNOSTICS, LLC. Group Development Sites

Tsukuba Research Institute, PAS Development Group

Utilizing polymerization, molding, blending and assembly

technologies, which are also all core technologies of the

Sekisui Chemical Group, we conduct R&D for vacuum

blood collection tubes and other related equipment used in

We conduct R&D for IVD products in the fields of clinical

chemistry, coagulation and infectious diseases that meet the needs of our customers in the US and Europe. Furthermore, clinical trials are conducted in order to introduce Japanese IVD products to US/EU markets.

the field of pre-analytical IVD



# Our Value 01

# Maximizing the value of pharmaceutical sciences through "Diagnostics"

From pre-treatment to post-treatment monitoring.

Diagnostics using specimen in the clinical setting play an important role in the early detection and the follow-up of treatment in various diseases such as malignant tumors, infectious diseases, and obstetric disorders. Sekisui Medical hopes that many people will obtain appropriate diagnoses through diagnostics and gain the best treatment efficiency. With this in mind, we are daily efforts towards our hopes.

#### For providing accurate treatment procedures

Clinical diagnostics, which are essential for pharmaceutical sciences, are performed in various situations, including diagnosis for prevention, diagnosis of pathological conditions, selection of treatment policies, measurement of medication efficiencies and prevention of deterioration during treatment, and monitoring after treatment. Diagnostics using specimen are essential for knowing the condition of each patient and choosing the best treatment. In our business of diagnostics using specimen, we provide automated analyzers and diagnostic reagents to clinical institutions worldwide. Especially in the segment of the coagulation testing, we have built a trusted relationship with our customers and have contributed to the pharmaceutical sciences in this segment for more than 20 years by providing analyzers and reagents for the measurement of coagulation factors and their breakdown products in the blood.



The diagnostics for coagulation, one of our strengths, is intended to measure the activity of protein breakdown products in the blood and substances involved in the clotting process. It is mainly used to monitor the presence and severity of blood clots. This diagnostics is also used to determine the condition of the body such as bleeding that does not stop before surgery, or to monitor therapeutic drugs.

Among the indicators of proteins indicating thrombosis formation, FDP and D-dimer have been considered difficult to measure due to

their complex molecular composition. They have a wide concentration range due to differences between patients and changes in pathological conditions. Since the diagnostics for coagulation is considered the first step in understanding a patient's condition and characteristics and determining future treatment guidelines, analyzers and reagents are required to provide fast and accurate results.

SEKISUI

### Automation allows us to contribute to efficiency in clinical setting and quality of testing for patients

Test results may vary depending on when the test was performed, even for the same patient. This means that diagnostics must be absolutely reliable to provide stable results. For approximately 30 years, Sekisui Medical has worked for automate diagnostics by partnership with instrument manufacturers , while producing reagents for automated analyzers and testing. The latest analyzer allows us to measure samples 400 times per hour, which significantly increases the measurement efficiency, reduces burden on clinical institutions' staff, accuracy and safety of the diagnostics have also greatly improved. For more than 20 years since their introduction, our products have helped improve the efficiency and quality of diagnostics in many clinical settings.





#### Meeting customer needs and creating a new value

Why have we been able to leverage our strengths in the segment of diagnostics for coagulation? The reason is that, from the beginning of the development phase, we have always considered what performance would be beneficial to patients and easy to use for clinical staff, and thoroughly developed our products. Our work is not completed when we deliver instruments and reagents to clinical institutions; the true value of our work is tested when users use our products. We, therefore, focus on customer support after the delivery of products and strive every day to respond to their inquiries and consultations to respond to their questions and requests.









#### Leveraging our strengths to create new value

Since the time when Sekisui Medical introduced automated products 20 years ago, the coagulation testing segment has evolved significantly. Nowadays, we are required to deliver products which provide not only the faster and more accurate test result, but also provide values that go beyond that. We take on a variety of challenges to leverage the resources and expertise we have accumulated so far. Our company helps to reduce the burden on clinical settings by improving the efficiency of not only the tests themselves, but also their management. To make the results easier to obtain, we have also released a simple desktop analyzer for medical practitioners that can display numerical results after the blood is dripped and placed into the analyzer. This analyzer can be used in a variety of clinical institutions including the hospital bedside and the medical practitioner's office. In addition to the existing diagnostics, we are working to address unmet medical needs in order to develop diagnostics that can test for rare diseases.



# Discovering invisible diseases and creating the smiles of tomorrow

No matter how medical science advance, there are still some diseases that cannot be completely treated. We believe that "every disease should be treatable." With this in mind, Sekisui Medical has been working in a daily basis to increase the value of the "diagnostics" that is used in the preliminary stage of treatment, to maximize the efficiency of treatment, and to increase the possibility of overcoming the disease as much as possible.

#### Treatment begins with "Diagnostic Tests"

In Japan, newborn screening tests are performed after the birth to determine whether the newborn has had a congenital disease or not. Currently, a newborn screening test examines 20 congenital diseases, allowing newborns who are found to have the disease to receive appropriate treatment. However, the current situation is that such rare diseases are still poorly treated. We will provide a supportive service related to child growth through clinical diagnostics accumulated in our history. For this purpose, Sekisui Medical has developed research reagents for screening rare diseases in collaboration with the National Center for Child Health and Development. The reagents have begun to be distributed to research institutions, hospitals and communities as diagnostics for expanded newborn screening. With our diagnostics, we can achieve early detection and treatment of rare diseases, recovery of symptoms and prevention of serious illness, thereby saving the lives of patients who can be saved and improving their quality of life thereafter.

#### Expanded newborn screening and Sekisui Medical services

#### What is an expanded newborn screening test?

Recently, the development of new therapeutic agents has led to the initiation of expanded newborn screening tests for diseases for which the prognosis can be improved if they are detected before the onset and treated early.



#### Services provided by Sekisui Medical

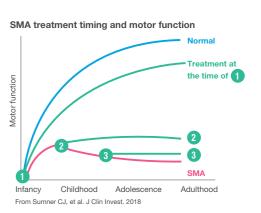
We currently have two proposals: contracting tests of expanded newborn screening and marketing of reagents. In the contracting tests, we receive requests for the tests from laboratories and perform clinical tests using the clinical diagnostics in our company. In the reagent marketing service, we supply our proprietary products to clinical institutions.

#### Target diseas

Marketing of reagents · Contract testing •Primary immunodeficiency •Spinal muscular atrophy Contract testing •Lysosomal storage disease(Fabry disease, Pompe disease, Gaucher disease, Mucopolysaccharidosis types I and II, etc.)

# To detect diseases that are life-threatening if not detected early

Sekisui Medical has developed and marketed NeoSMAAT T/K/S, a diagnostic test kit, which simultaneously screens for two diseases: primary immunodeficiency and spinal muscular atrophy. The overall incidence is 1:10,000 live births for primary immunodeficiency and 1:20,000 live births for spinal muscular atrophy; it is considered important to perform screening tests in the neonatal period to confirm the presence of these diseases to maximize the effectiveness of treatment. It is no exaggeration to say, therefore, that this screening test will have a significant impact on the future lives of infants and young children.



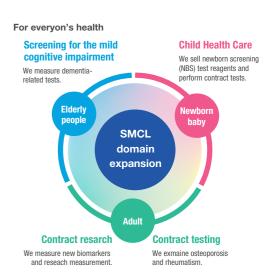
#### To achieve faster, more accurate test results

Due to the nature of rare disease, the diagnostic tests and treatment may take longer than for other diseases. Thus, the test results should be shown as quickly and accurately as possible. We have developed a test method that allows testing directly from dried blood spot to successfully reduce the testing time by approximately half. At the same time, this process reduction can reduce the risk of errors and the cost of testing. We have been able to lower the bar in terms of test accuracy and cost and make this screening test available to more newborns.



### Contributing to the health of all people and society through screening tests

"To provide intelligent solutions to enhance life with science and improve the health of all people" With this mission, Sekisui Medical will also contribute to the health of adults and the elderly through screening tests in this diagnostics segment. Moreover, we will offer diagnostics that uses technology to screen for a variety of diseases including dementia, as well as one that diagnoses the therapeutic efficiency on rheumatoid arthritis and osteoporosis. Treatment begins with "Diagnostic Tests." Sekisui Medical will continue to strive to expand the diagnostics segment and improve its efficiency so that its products and services provide value to patients, their families and society as a whole.



#### oice.

Voices in the clinical setting

#### Making life the best for newborns and their families

Early detection and treatment of the rare diseases targeted by the xpanded newborne screening test are important and have great significance for newborns and their families. As a clinician, I have encountered newborns whose screening tests revealed severe immunodeficiency or lysosomal storage disease and found them to be thriving and healthy thereafter with the early intervention. So, I am acutely aware of the value and importance of these screening tests on a daily basis. I believe that the value of these tests is wide-ranging, as the results of tests are not limited to the newborn, but may also lead to health care for his/her family. But the further penetration of the screening tests into the families of newborns and into actual medical practice is a major challenge for the future. It is also true that there are disparities among regions and clinical institutions that perform these tests. Accordingly, I'd like to strongly accelerate our efforts with Sekisui Medical to promote understanding of the screening tests so that as many newborns as possible can receive them.



Department of Pediatrics, Niigata University Medical and Dental Hospital

Dr. Hiromi Nyuzuki



#### Building a foundation for a new drug development

As medical needs have diversified with the evolution of pharmaceutical sciences, we are expected to respond to various types of disease.

Under such circumstance, the roles and expectations of medicines which protect lives are growing, there is a constant need for absolute safety, security, and speed to deliver them as quickly as possible. Society also demands that we develop medicines with new efficacy for diseases that cannot be treated before with conventional medicines. As a contract manufacturing organization in this pharmaceutical field, we support the foundation to produce active pharmaceutical ingredients (APIs), which form the basis of drugs, and investigational drugs for clinical trials to support the development of new medicines.

#### Flow of Contract Manufacturing Organizations and Sekisui Medical's domain

#### What is a Contract Manufacturing Organization?

Contract manufacturing organizations (CMOs) are companies that contract with pharmaceutical companies to manufacture drugs (including investigational drugs and over-the-counter drugs). Thus, pharmaceutical companies, which incur huge costs to develop new drugs, outsource the manufacturing process to CMOs in order to focus their resources on drug discovery and clinical development. To produce pharmaceutical products, we must have quality systems and equipment that meet manufacturing standards called Good Manufacturing Practice (GMP).

The Drug Development Process and the Role of CMOs



#### Our domain

- •API manufacturing •Pharmaceutical intermediate manufacturing
- Investigational drug manufacturing

## Supporting the development carried out by pharmaceutical companies and raising the possibility for new drugs

The origin of our pharmaceutical development lies in the technologies that we have developed over the years for the synthesis of amino acids and the production of optically active compounds. We have used these technologies to transform our business into APIs manufacturing to expand the scope of our contributions to drug development. Currently, we have developed contract manufacturing of active pharmaceutical ingredients (APIs) and pharmaceutical intermediates. As a CMO, we support drug development from a manufacturing perspective so that new medicines can reach patients quickly and safely, helping to cure diseases and improve patients' quality of life.



#### Absolute security, guaranteed fast delivery

We collaborates with pharmaceutical companies to bring new medicines to market as quickly as possible for many patients who are waiting for them, as well as to achieve their health. Therefore, we must ensure the absolute safety and high quality of our APIs and intermediates. In order to achieve these goals, we comply with regulations of each country, strictly adhere to GMP-based manufacturing procedures and quality control, and pass global inspections and audits during manufacturing.

In addition, we have established a top-class data integrity system in Japan that is used for quality control of various APIs and intermediates. For these electronic records, we are prepared to ensure the protection and accessibility of accurate and complete records for a specified retention period, and to provide high quality and security at all times.



# Meet all needs and maximize value for patients

In order to respond to various diseases, more emphasis has been placed on shortening the time from R&D of drugs with new efficacies to marketing and delivery to patients. Therefore, the CMOs must have the ability to develop and manufacture in a timely manner in accordance with the pharmaceutical company's development plan. We have many R&D, manufacturing staff and a variety of equipment. In 2023, We have increased our production capacity to meet additional medical needs and new contracts from customers with the addition of the intermediates manufacturing plant. We also have multiple production lines for APIs conform to GMP, including investigational drugs, to meet demand at all scales from investigational to commercial manufacturing. By providing support from R&D to commercial manufacturing, We will continue to respond to customer and medical needs and contribute to the realization of new medical solutions.



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# Sustainability

To achieve sustainable growth, Sekisui Medical engages in sustainability activities to improve the quality of our business while fulfilling our social responsibilities and creating value according to the SEKISUI CHEMICAL Group Vision.

#### For the global environment

#### the Sekisui Medical Environmental Charter

We strive to be a company that creates a healthy environment, and that achieves sustainable growth with 'the environment' as our cornerstone.

To achieve this goal:

- 1) Each one of us pays due consideration to the environment in our actions at work.
- 2) Each one of us also engages in environmentally-friendly action at home and in the local community.

#### To realize a decarbonized society

Sekisui Medical has set a long-term goal of achieving zero greenhouse gas (GHG) emissions by 2050 in order to realize a decarbonized society. To achieve this goal, we are promoting GHG reduction activities through the effective use of energy through the installation of energy-saving and high-efficiency facilities, and the installation of renewable energy generation facilities. Specific initiatives include the conversion of boiler fuel from heavy oil to LNG (switching to low-GHG emission fuels), the installation of high-efficiency boilers and a solar power generation systems, and the conversion of purchased electricity to 100% renewable energy. The medium-term goal is to reduce GHG emissions by 50% from the

FY 2019 level by FY 2030. In FY 2024, two domestic plants and all research institutes completed the conversion to renewable energy sources and achieved zero GHG emissions from electricity.

In addition, we have assigned persons who are certified as "Environment Legal Leader (ELL)" by Sekisui Chemical Group to each business establishment, and is working to comply with environmental laws and regulations and prevent environmental incidents.



Solar power system at Tsukuba Plant



LNG Fuel Tank at Iwate Plant

#### Our Commitment to the Environment

Tsukuba Plant	The Tsukuba Plant is located in the Tsukuba-no-sato Industrial Park in Ryugasaki, Ibaraki Prefecture, and manufactures in vitro diagnostics along with reagents for research use. The Plant implements environmentally friendly measures including the use of renewable energy, the cultivation of native plant species, and the removal of introduced plant species. It acquired ISO 14001 Environmental Management System certification in September 2011 (assessment and registration) and actively engages in efforts to protect the environment.
Ami Office	The Ami Office is located in the Fukuda Industrial Park in Ami-machi, Inashiki-gun, Ibaraki Prefecture. It manufactures in vitro diagnostics and reagents for research use. The office implements environmentally friendly initiatives, such as the energy-saving operation of its manufacturing equipment, garbage separation and processing, and clean up campaigns. The Ami Office acquired ISO 14001 Environmental Management System certification in May 2006 (assessment and registration) and actively engages in efforts to protect the environment.
Tokuyama Plant	The Tokuyama Plant is located in the Shunan Industrial Complex in Yamaguchi Prefecture, and manufactures vacuum blood collection tubes, diabetes diagnosis columns, and eluents. The Plant has reduced waste and since 2000 has been maintaining a forest leased from Shunan City. In March 2000, the plant obtained the ISO 14001 environmental management system certification (assessment and registration), and is committed to environmental protection.
lwate Plant	The lwate Plant is located in a scenic area with views of the majestic mountains of Towada-Hachimantai National Park, offering a setting rich in natural beauty. All electricity used at the plant is derived from 100% renewable energy sources, reflecting our strong commitment to environmental sustainability. We have implemented a range of eco-friendly initiatives, including the installation of LNG boilers and the effective utilization of methane gas generated from our wastewater treatment system. These efforts are part of our broader mission to coexist harmoniously with the irreplaceable natural environment surrounding the plant. In addition, the plant obtained ISO 14001 in February 2001 certification and has since been continuously developing its environmental management system. In 2023, it was certified one of the "Nationally Certified Sustainably Managed Natural Sites" by Japan's Ministry of the Environment, and continues to pursue environmentally conscious production activities.
Drug Development Solutions Center	The Drug Development Solutions Center is located in Tokai-mura, Ibaraki Prefecture, and conduct safety studies of pharmaceuticals. The Center is involved in a number of environmental initiatives, including the installation of LNG boilers, the use of renewable energy, waste separation, the reduction of copier paper usage, and the implementation of a clean up campaign. The Plant acquired ISO 14001 Environmental Management System certification in July 2024 (assessment and registration) and actively engages in efforts to protect the environment.

#### **Initiatives for society**

#### Our approach to Quality

#### CS Quality Management

CS Quality is our management cornerstone. In all of our business activities, we seek meticulously innovations to improve product quality, and provide products and services that live up to customer expectations. We want our customers to continue to choose us, and aim at to achieve long-term growth and sustainable development along with our customers.

Diagnostics Business	The Tsukuba Plant has established a quality management system based on the QMS Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics to supply high-quality products worldwide. We continue to hold ISO 9001 certification (acquired in March 1997) and ISO 13485 certification (acquired in March 2005). In 2017 the Ami Office was added to the Tsukuba Plant as a new manufacturing base, and we completed the update to ISO 9001:2015 and ISO 13485:2016. The Tokuyama Plant has also established a similar quality management system based on ISO 13485 (acquired in April 2005) and ISO 9001 (acquired again in March 2025 following the succession of business from Tokuyama Sekisui Co., Ltd.).
Pharmaceuticals Business	Based on ministerial ordinances with regard to GMP for pharmaceuticals and medicated products, the lwate Plant manufactures high-quality chemicals, with a particular focus on APIs, pharmaceutical intermediates, and food additives. We are registered with the American FDA and official bodies in the EU and elsewhere, and we ship APIs not only within Japan but also to the global market.
Drug Development Solutions Business	The Drug Development Solutions Center has conducted Preclinical drug safety studies in accordance with the Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Drugs (GLP Ordinance). The Center has received a conformity of assessment/results in the survey on toxicokinetics (TK) test by the Pharmaceuticals and Medical Devices Agency while assisting pharmaceutical companies in Japan and overseas in the development of new drugs.

#### Our approach to Human Resource Development

#### Our approach to Human Resource Development

Based on our belief that employees are precious assets bestowed on us by society, we, SEKISUI CHEMICAL Group, are committed to developing an environment where employees can work enthusiastically. We also offer various opportunities through which we help individual employees enhance their specialties and grow personally through embracing challenges.

Sekisui Medical has established "Customer Focus" as one of its values to achieve the Group vision of "Creating a Healthy, Sustainable World." We launched the Customer Focus Project in 2021, which includes activities such as discussions between sales and other sites, hands-on training at sales and production sites, and temporary assignments to other departments. Through the project, we make the value of customer focus take root among our employees, while also allowing them to experience firsthand helping to solve social challenges.

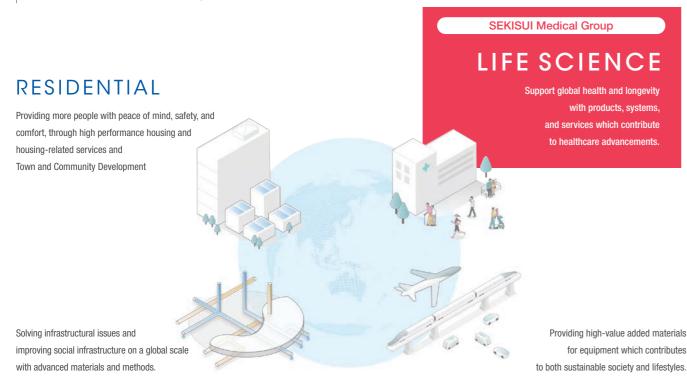
#### Deepening Engagement

SEKISUI CHEMICAL Group periodically conducts the engagement survey targeting all employees every three years. We assert that continued empathy with and undertaking of our Vision, as well as each individual employee is always the key players; the sense of belonging in the company, passion for work and willingness to contribute, in other words engagement, is crucial for achieving the SEKISUI CHEMICAL Group Long-term Vision, Vision 2030.

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Sekisui Chemical Group Business Domain



ADVANCED LIFELINE

INNOVATIVE MOBILITY

with products, systems,

Providing high-value added materials

for equipment which contributes

to healthcare advancements.

# **Corporate History**

Chemicals

Foundation of Daiichi Pure Chemical Co., Ltd. Start of domestic production of in vitro diagnostic reagents. Established the first private sector radioisotope laboratory Started production and sales of amino acids Released the first ever domestically-produced radiopharmaceuticals Started contract safety research business Became a wholly owned subsidiary of SEKISUI Chemical through transfer of shares owned by Daiichi Pharmaceutical

SEKISUI Medical established by merging the Medical

Business Division of SEKISUI Chemical with Daiichi Pure

Establishment of SEKISUI Medical Technology (China)

Acquired the Diagnostic Pharmaceuticals Division of Genzyme 201 Corporation and established SEKISUI Diagnostics

Established SEKISUI Medical Technology (Suzhou) Acquired Eisai in-vitro diagnostics subsidiary EIDIA

Merged SEKISUI Medical and EIDIA

SEKISUI Chemical acquired Veredus Laboratories

Acquired medical business from Tokuyama Sekisui Industry Co., Ltd. and newly established Sekisui Medical Co., Ltd. Tokuyama Plant.

#### Company Overview

SEKISUI MEDICAL CO., LTD. Company Name **Fstablished** April 1, 2008 Capital

1.275 billion yen Hiroyuki Yamashita President & CEO

**Head Office** Nihonbashi 2-1-3, Chuo-ku, Tokyo **Our Business** 

**Annual Sales** 

Stockholder

Diagnostics Business, Pharmaceuticals Business, Bio CDMO Business, Drug Development Solutions Business 67.8 billion yen (for the fiscal year ending on March 31, 2025)

Sekisui Chemical Co,. Ltd. (100% stockholder) Fiscal year-end March

Number of employees 1,545 (as of April 1, 2025)

#### Sekisui Medical in Numbers

Consolidated Net Sales (FY2024)

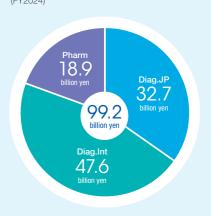
Consolidated Operating Income

Number of Sekisui Medical Group Employees

Number of Sekisui Medical

Group companies

Sales ratio by business segment



Ratio of male and female employees of Sekisui Medical Co., Ltd.

Ratio of male and female employees taking childcare leave

Male 62 % Female 38 % Male 75 % Female

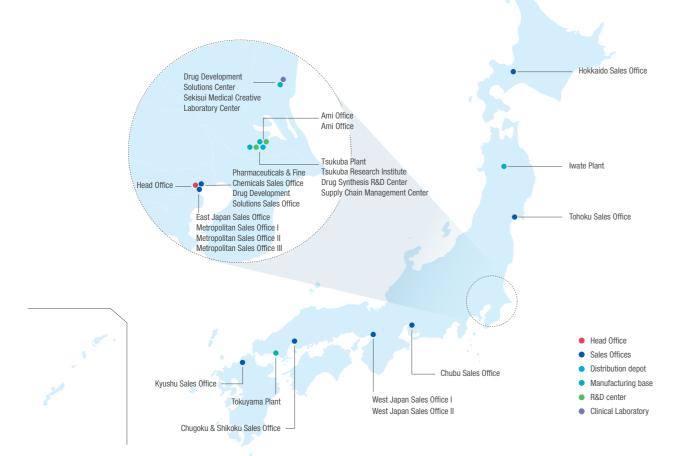
Usage rate for annual paid leave

Ratio of remote working (head office)

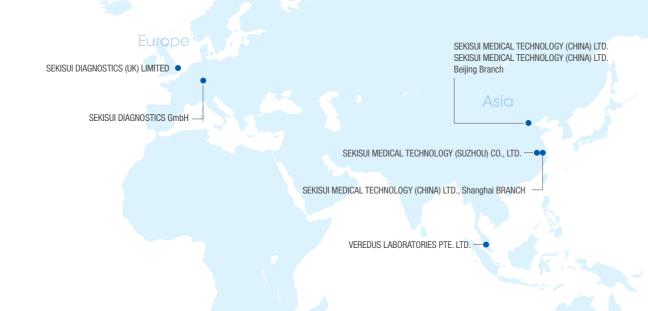
Ratio of female managers

15 16

# Domestic Network



# Overseas Network



Head Office Urban Net Nihonbashi 2-chome Building, Nihonbashi 2-1-3, Chuo-ku, Tokyo 103-0027 Japan

Sales Offices

Hokkaido Sales Office

Sapporo Center Building 7F, Kita 5 Jonishi 6-2-2, Chuo-ku, Sapporo 060-0005 Japan

Tohoku Sales Office

Taiju Seimei Sendai Honcho Building 18F, Honcho 1-1-1, Aoba-ku, Sendai 980-0014 Japan

East Japan Sales Office/Metropolitan Sales Office I-III
TOC Ariake East Tower 8F. Ariake 3-5-7, Koto-ku, Tokyo

135-0063 Japan Chubu Sales Office

Nagoya Itochu Building 3F, Nishiki 1-5-11, Naka-ku, Nagoya 460-0003 Japan

West Japan Sales Office I-II

Uemura Nissei Building 16F, Miyahara 3-3-31, Yodogawa-ku, Osaka 532-0003 Japan

Chugoku & Shikoku Sales Office

GRANODE Hiroshima 6F, Hutabanosato 3-5-7, Higashi-ku, Hiroshima 732-0057 Japan

Kvushu Sales Office

Kyu-kan Hakata Building 2F, Hakataekimae 3-26-29, Hakata-ku, Fukuoka 812-0011 Janan

Pharmaceuticals & Fine Chemicals Sales Office

Urban Net Nihonbashi 2-chome Building, Nihonbashi 2-1-3, Chuo-ku, Tokyo 103-0027, Janan

Drug Development Solutions Sales Office

Urban Net Nihonbashi 2-chome Building, Nihonbashi 2-1-3, Chuo-ku, Tokyo 103-0027 Japan

Distribution depot

Supply Chain Management Center Koyodai 3-3-1, Ryugasaki, Ibaraki 301-0852 Japan

Manufacturing

Tsukuba Plant Koyodai 3-3-1, Ryugasaki, Ibaraki

301-0852 Japan

Yoshiwara 3262-12, Ami-machi, Inashiki-gun, Ibaraki

300-1155 Japan

Tokuvama Plant

Kaiseicho 4560, Shunan-shi, Yamaguchi 746-0006 Japan

Iwate Plant

Matsuo 4-115, Hachimantai, Iwate

28-7305 Japan

Drug Development Solutions Center

Muramatsu 2117, Tokai-mura, Naka-gun, Ibaraki

319-1182 Japan

R&D Tsukuba Research Institute
Center Kovodai 3-3-1 Byugasaki Ibaraki

Koyodai 3-3-1, Ryugasaki, Ibaraki 301-0852 Japan

Yoshiwara 3262-12, Ami-machi, Inashiki-gun, Ibaraki

300-1155 Japan

Drug Synthesis R&D Center

Koyodai 3-3-1, Ryugasaki, Ibaraki

301-0852 Japan

Clinical Laboratory Sekisui Medical Creative Laboratory Center Muramatsu 2117, Tokai-mura, Naka-gun, Ibaraki

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319-1182 Japa

