

Kyowa Hakko Kirin Group

Corporate Social Responsibility Report 2011

KYOWA KIRIN

Customers

Shareholders,
investors

The Group Management Philosophy

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

Employees

Society

Global
environment

C O N T E N T S

Editorial Policy

The Kyowa Hakko Kirin Group Corporate Social Responsibility Report outlines the diverse range of activities performed by the group to provide value to society and give expression to our Group Management Philosophy.

This year's report features an interview with President Yuzuru Matsuda in the Management Commitment section, where he talks about the activities conducted by the group to realize its Management Philosophy along with the roles we expect to fulfill through our promotion of CSR. The report also includes special feature articles in which group company employees engaged in various duties in and outside Japan express their enthusiasm about working for the improvement of human health and well-being. The overall composition of the report is designed to introduce our CSR activities on a stakeholder-by-stakeholder basis. It closes with several third-party comments on the report and our head of CSR's response to them. Since our economic activities are largely covered by our securities reports and annual reports, only minimal coverage of these is provided in this report.

Scope of the Report

This report primarily presents information on Kyowa Hakko Kirin and its consolidated subsidiaries in Japan, but also includes information on some overseas subsidiaries. Environmental performance data was gathered from the production and R&D sites of Kyowa Hakko Kirin and its consolidated subsidiaries in Japan, except for the Material Balance data on page 31, which includes data on overseas production sites. Green Office Plan data for sales offices in Japan is also included. Reflecting the unique nature of its business, the environmental activities of Daiichi Fine Chemical are reported separately. Although we transferred all the shares of Kyowa Hakko Chemical to KJ Holdings Inc. in March 2011, this report includes the fiscal 2010 data for Kyowa Hakko Chemical.

Period Reported

The period covered by this report is from January to December 2010, although some activities conducted in fiscal 2011 are also referred to.

The environmental performance reported in this report is based on data collected from April 2010 to March 2011 for Japan and from January to December 2010 for overseas.

Published in September 2011

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* The English edition of the Kyowa Hakko Kirin Group Corporate Social Responsibility Report is distributed online only.

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Management Commitment

Our Group is United in its Goal to Contribute to Human Health and Well-being

Yuzuru Matsuda

Yuzuru Matsuda
President & Chief Executive Officer
Kyowa Hakko Kirin Co., Ltd.



First and foremost, we would like to offer our deepest condolences and heartfelt sympathies to the victims of and all the people affected by the Great East Japan Earthquake of March 11. We also express our utmost gratitude for the warm support and encouragement extended to us from countries around the world. We sincerely do hope that the stricken areas recover swiftly from the disaster.

The earthquake severely damaged some of our contracted manufacturers and cut off our logistics and communications lines. As a pharmaceutical company providing medicines for patients, we have been reminded of the significance of our mission to ensure a stable supply of products. Based on the lessons learned from this disaster, we will review all existing systems and manuals pertaining to production, inventories, logistics, and other functions throughout the supply chain to optimize our crisis management so that we are able to deliver medicines wherever it is needed even in the event of a disaster.

Q What specific activities is the group conducting to give expression to the Management Philosophy?

We are maximizing the synergies of group companies

In our Group Management Philosophy, we promise to contribute to “the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.” We also endeavor to maintain highly transparent business management by paying particular attention to quality, environment, safety, and compliance.

In order to realize our Group Management Philosophy, Kyowa Hakko Kirin aspires to become one of the world’s best global specialty pharmaceutical companies focused on the areas of oncology, nephrology, and immunology, based on the biotechnologies we have accumulated up until this point. Our aim is not to compete to become large but to become the leader in our areas of specialization. We believe that this is the best way to fully demonstrate our strengths.

Looking back over the past year, Kyowa Hakko Kirin completed the construction of facilities for the production of an investigational therapeutic antibodies in Takasaki City, Gunma Prefecture in 2010 and submitted a new drug application (NDA) to the Ministry of Health, Labour and Welfare for KW-0761, an antibody used for the treatment of adult T-cell leukemia-lymphoma (ATL), on April 26, 2011. The ProStrakan Group Plc, a U.K.-based pharmaceutical company joined Kyowa Hakko Kirin Group, resulting in the expansion of the group’s network beyond Asia and into the global arena. In the area of R&D, we worked to develop a cross-company and cross-border cooperation system. For Kyowa Hakko Kirin, the past 12 months was a year in which the group made a great stride forward to achieve our goal of becoming a leading global specialty pharmaceutical company.

Kyowa Medex developed *in vitro* diagnostics jointly with Kyowa Hakko Kirin, for which an NDA was submitted

at the same time as the one for KW-0761. The use of this diagnostic allows doctors to examine whether or not KW-0761 is likely to work in particular patients before the antibody is administered. The reagents are also expected to increase the efficiency of clinical trials and speed up the development process. This kind of integrated patient diagnosis and treatment technique is becoming the norm in medical practice. I am therefore confident that the partnership with Kyowa Medex, a company that has been devoted to the development of *in vitro* diagnostics and diagnosis equipment since its foundation, will be increasingly fruitful in the future.

Kyowa Hakko Bio is one of the very few companies in the world capable of producing almost all types of amino acids using fermentation methods. Amino acids are contained in infusions used for alimending patients, and constitute an indispensable nutrient component of cell culture media used for the manufacture of therapeutic antibodies and bio-pharmaceuticals. Amino acids are also widely utilized around the world in dietary supplements and health foods, which people take to maintain their health and improve their quality of life. Most pharmaceuticals are chemically synthesized at present, but pharmaceuticals derived from organisms, or bio-pharmaceuticals, are expected to increase in the future. I am confident that Kyowa Hakko Bio’s technologies will assume an important role in that trend.

These three companies make up our business portfolio, which is so unique that no other company in the world can boast one like it. To realize our Group Management Philosophy, these three companies need to make the most of their respective strengths while maximizing their combined synergies.





Q What are the corporate social responsibilities of the Kyowa Hakko Kirin Group?

Our mission is to become a truly unique company

To offer a steady and continuous supply of innovative, unique, and unrivalled pharmaceuticals and related products for the treatment of intractable diseases through the exploitation of cutting-edge technologies is our main social responsibility and the most valuable social contribution we can make. Our ultimate goal with respect to CSR is to become a truly unique company that is valued by society as indispensable.

Profits earned need to be reinvested in R&D and used to upgrade our plants and obtain licenses for needed technologies and products so as to further enhance our business and thereby promote social contributions. This is how we increase our corporate value. Increased corporate value leads to more benefits for stakeholders.

There are still many patients suffering from diseases for which no effective treatment yet exists. These people are waiting on the development of new drugs. We therefore need to deliver as many drugs as possible within the quickest possible time. In achieving this, Kyowa Medex's in vitro diagnostics and Kyowa Hakko Bio's bulk pharmaceuticals, intermediates, and amino acids will play an important role, as will our other businesses that support drug discovery and development. It is my belief that the efforts of each company to fulfill its respective mission and develop its business both in terms of quality and size are the key to accomplishing our CSR.

Q How do you expect employees to embody the Group Management Philosophy and promote CSR?

We seek to be more cosmopolitan and global-oriented

We need to be more global-oriented in order to contribute to "the health and well-being of people around the world." As a matter of fact, this year has seen the Kyowa Hakko Kirin Group further advancing its move toward globalization with the expansion of its network outside Asia through collaboration with the ProStrakan Group. With the addition of the 350 employees of the UK-based company, the number of our overseas local employees now totals 1,100. For our employees both in Japan

and overseas, there will be more opportunities to work in different regions. Needless to say, we need to improve our work environment so that every employee, regardless of nationality, race, or gender, can reach their full potential and have their performance evaluated fairly.

Being cosmopolitan does not necessarily mean being fluent in another language. Even if you don't have good language skills, you still can deepen your relationship with local staff in foreign countries if you are flexible, open and able to respect different values. In other words, "will" is more important than "skills" in those seeking to be truly cosmopolitan. Even those working at Head Office need to be aware that it is the headquarters of our global operations, not just of our domestic operations.

The other point I want to make concerns our mission statement, which is titled "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin." This statement was created by considering how we would feel if someone we loved came down with serious illness. In such circumstances everyone would wish that they had a remedy or the skills to cure the disease.

We are all professionals in the fields of R&D, production or sales and are proud of our work. In order for our products to be useful, however, they must be delivered and administered to patients—tasks that lie outside our area of expertise. In fact, we seldom have the chance see how the drugs we make are used in actual medical settings. At the same time, we have not been able to sufficiently communicate to doctors working in clinics and hospitals how much effort and time we put into developing the pharmaceuticals. To bridge this gap, I think we need to strengthen communication with those working directly with patients at medical institutions.

One idea I have in mind is to place employees in the frontlines of actual medical practice during early years of their career as part of new employee training or volunteer activities so that they can understand the feelings of both patients and their families and doctors and other medical personnel. This will also allow employees to see how our products contribute to society and help enhance their motivation. I believe this kind of experience is important not only for employees of Kyowa Hakko Kirin, who are involved in pharmaceuticals business, but also for employees of Kyowa Medex and Kyowa Hakko Bio. Uniting the mind-set of all employees and working in concert is, in my view, the only way we can realize the Group Management Philosophy and accomplish our CSR.

Our mission statement
Sharing Values, Aims, and Ideals;
Team Kyowa Hakko Kirin

"Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin" is the mission statement of Kyowa Hakko Kirin, created when the company was established in October 2008. The statement expresses the strong determination of each employee to devote themselves to saving the lives of all who are suffering from disease, and save society through the development of new drugs.



"Sharing Values, Aims, and Ideals;
Team Kyowa Hakko Kirin"
is printed in card form and
distributed to all employees.

Here at Kyowa Hakko Kirin, an abiding respect for life, health, and wellness inspires everything we do. First and foremost, we work to protect and improve the lives of those who depend upon our products. As an up-and-coming pharmaceutical supplier and a driver of health care innovation, we are well-positioned to make a significant impact on public health. We intend to devote all of our resources and capabilities to this worthy goal.

Believe in Ourselves

Let us place our trust in our experience and our substantial shared pool of knowledge. Although we certainly are not the largest pharmaceutical firm, we possess a unique combination of core competencies and capabilities that are unparalleled in the market. Let us draw upon and sustain our history, our legacy, our technological prowess and our unsurpassed knowledge resources. The possibilities of what we can accomplish as a pharmaceutical company are infinite.

Strive to Be Fearlessly Innovative

The path to excellence is neither smooth nor linear. Let us have the courage to identify and overcome difficulties, the passion to reach beyond the conventional way of doing things, and the integrity to recognize and learn from missteps. Innovation is not simply the maturation of ideas; it is a leap of growth that can only be achieved through diligence, a daring dedication to progress, and a willingness to transcend the status quo.

Support Wellness and Quality of Life

Let us endeavor to go beyond just making medicine. Health is more than just the absence of illness, and our work should be carried out with a solemn awareness that wellness and quality of life are equally worthy goals. And, let us engender happiness. Think always of the families whose ailing loved ones depend on us, and support the health care practitioners who strive tirelessly to save lives. Innovative research and business insight are not enough to help us fulfill our mission—we must cultivate kindness, empathy, and sensitivity to the problems facing humanity, as well.

Find Strength in Numbers

Let us aim to become the ultimate team. No matter how talented an individual may be, alone he or she is hardly perfect. Let us take our energy, enthusiasm and pioneering spirit to join as one. Through our combined strength, we can yield unimaginable solutions. This is what we want to show the world.

Accelerate Our Efforts

Let us carry out our work while raising our awareness of the scale of patients' suffering from the diseases that we combat. Each day, lives are lost and families are torn apart by illnesses that our research and products can help to eradicate. The challenge may be overwhelming, but our efforts must be ceaseless—there can be no rest along the way.

Pursue Our Objectives with Honesty and Integrity

At all times and in all things, let us comport ourselves and make decisions in a manner that is consistent with our mission. As a manufacturer of medicine, our company's very survival depends on our customers' implicit trust. Countless lives hang in the balance; let us make a vow to act always with the integrity this mission demands.

Celebrate and Take Pride in Our Shared Mission

The Kyowa Hakko Kirin team comprises a talented group of professionals who hail from all over the globe. Through a remarkable confluence of events, we have all come together to share in this work, forming a unique synergy of hearts and minds in the process. Even though we face difficult challenges, let us also appreciate the opportunity to help protect and improve people's lives.

Let us harness our passion to serve humanity and shape the future. Let us walk the path of hope for every precious life.

We are Kyowa Hakko Kirin. For each life, we are here.

Our Pharmaceutical and Health Care Businesses Contribute to the Health and Well-being of People around the World through Leading-edge Biotechnology

The Kyowa Hakko Kirin Group consists of about 40 companies worldwide, out of which there are three major companies in Japan: Kyowa Hakko Kirin, the core company of the group whose main mission is to create innovative new drugs; Kyowa Hakko Bio, a manufacturer of amino acids for use in bulk pharmaceuticals and infusions; and Kyowa Medex, a major player in the area of *in vitro* diagnostics. All these companies are united in the goal of seeking to contribute to the health and well-being of people around the world by offering a wide range of products based on leading-edge biotechnology.

Kyowa Hakko Bio

Developing amino acids for use in health care

By exploiting its innovative fermentation production technologies, Kyowa Hakko Bio commercializes amino acids, nucleic acid-related substances, vitamins, physiologically active substances, and other beneficial substances. The company is playing a key role in meeting increasing global demands for value-added amino acids for pharmaceuticals as well as the needs of the specialty generic pharmaceuticals market. It supplies raw materials for pharmaceuticals and cosmetics, health foods and their raw materials, and other products that contribute to human health and well-being.

Major products:
pharmaceutical raw materials,
health care products



More details on page **16**

Kyowa Medex

Offering *in vitro* diagnostics and medical instruments for the prevention and treatment of diseases

Kyowa Medex plays an important part in Kyowa Hakko Kirin's Pharmaceuticals business, as well as in bringing health and well-being to people around the world, through the development, production, and sale of *in vitro* diagnostics and medical instruments. The company's products include reagents for use in the measurement of cholesterol and neutral fat for the diagnosis of hyper-lipidemia; reagents for HbA1c measurement to examine blood glucose control levels; and reagents and instruments for the measurement of fecal occult blood to screen for colorectal cancer.



Major products:
in vitro diagnostics, medical instruments

More details on page **14**

B i o t e c h n o

Company Profile (as of April 1, 2011) *Excluding Kyowa Hakko Chemical Co., Ltd., whose shares were transferred in March 2011

Company Name: Kyowa Hakko Kirin Co., Ltd.

Head Office: Ohtemachi Bldg., 1-6-1 Ohtemachi, Chiyoda-ku, Tokyo 100-8185, Japan
Phone: +81-3-3282-0007

Date of Foundation: July 1, 1949
(Trade name changed from "Kyowa Hakko Kogyo Co., Ltd." on October 1, 2008, upon the merger with Kirin Pharma Company, Limited.)

Number of Employees: 7,484 (consolidated), 5,041 (parent company) (as of December 31, 2010)

Paid-in Capital: ¥26,745 million

Major Consolidated Subsidiaries: Kyowa Hakko Bio Co., Ltd., Kyowa Medex Co., Ltd.

Representative: Yuzuru Matsuda,
President and Chief Executive Officer

Main Businesses: Pharmaceuticals (manufacture and sale of ethical drugs and *in vitro* diagnostics)
Bio-chemicals (manufacture and sale of pharmaceutical and industrial raw materials, health care products, and products for agriculture)
Other (wholesaling, transportation)

Contributing to the health and well-being of people around the world

Kyowa Hakko Kirin

Developing new drugs in the areas of oncology, nephrology, and immunology

Following the merger of Kyowa Hakko and Kirin Pharma, two companies in possession of leading-edge biotechnology, Kyowa Hakko Kirin was established in October 2008 to produce and market ethical drugs. The company is currently working with more than 50 types of pharmaceuticals, including anemia drugs that stimulate erythrocyte production, anti-allergic drugs that are effective against pollen allergies, and anti-cancer agents. In the area of therapeutic antibodies, Kyowa Hakko Kirin has developed a unique technology that boosts the activity of antibodies and licensed it out to many pharmaceutical companies. The company's aim is to become a Japan-based global specialty pharmaceutical company that is capable of stably and continuously delivering innovative new drugs, mainly in the areas of oncology, nephrology, and immunology, and bringing health and well-being to people around the world.

Major products:
ethical drugs

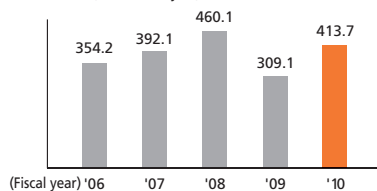


More details **11**
on page

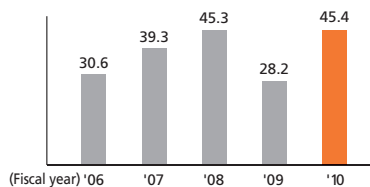
Financial Highlights (Kyowa Hakko Kirin's consolidated financial results)

*Due to the change in the fiscal year end, fiscal 2009 data shown below covers a period of only nine months, from April 1 to December 31, 2009.

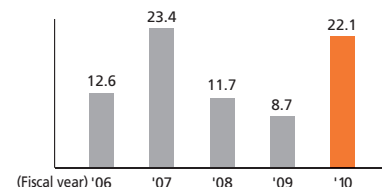
Net sales (Billions of yen)



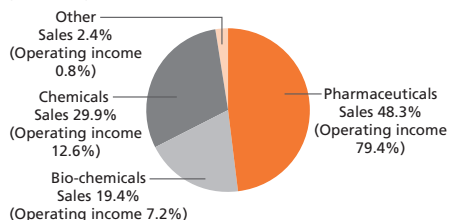
Operating income (Billions of yen)



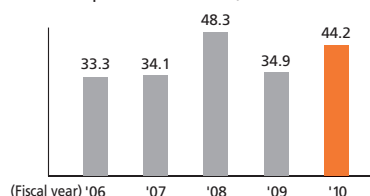
Net income (Billions of yen)



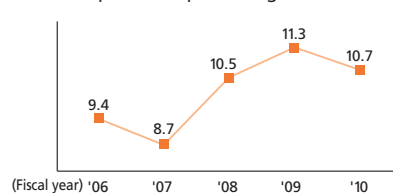
Sales and operating income composition by business (fiscal 2010)



R&D expenses (Billions of yen)



R&D expenses as percentage of net sales (%)



Developing and Maintaining Integrity

Strengthening Ethical Governance and Risk Management to Become an Even More Trusted Company

Corporate Governance

We conduct our business under a management system and organization established to facilitate the realization of our Group Management Philosophy. We are also working hard to maintain the highest standards of corporate governance to ensure increased transparency and effective management oversight.

Strengthening corporate governance and internal control

Kyowa Hakko Kirin's management structure is centered on the Board of Directors and the Board of Auditors, organs required by the Companies Act for stock companies (classified under the act as a "Company with Auditors"). The Board of Directors consists of nine directors, three of whom are external directors, and the Board of Auditors consists of five corporate auditors, four of whom are external corporate auditors (as of the end of March 2011). In accordance with the audit policies determined by the Board of Auditors, the corporate auditors attend important meetings, including meetings of the Board of Directors. They also audit the performance of the directors' duties by investigating the company's operations and finances. As advisory groups to the Board of Directors, the Remuneration Consultative Committee and the Nominating Consultative Committee, each composed of four directors including external directors, provide objective and fair advices and recommendations regarding remuneration and nomination of directors and auditors to the Board of Directors. The Corporate Strategy Meeting has also been established to make strategic management decisions in an efficient manner.

To maintain the appropriateness of our business operations, the Board of Directors periodically reviews its policies on, and the current status of, the development of the group's internal control system to assure continuous improvement of the system. The Internal Audit Department, which oversees internal auditing, works with the corporate auditors to conduct audits of business

operations across the Kyowa Hakko Kirin Group and monitor compliance with laws, regulations, and the Articles of Incorporation, with a view to also enhancing management efficiency.

Risk management through in-house committees

Kyowa Hakko Kirin has various in-house committees in place to deal with a variety of risks inherent in management decisions as well as issues of corporate governance. The committees regularly report on their activities to the Board of Directors. The main function of each committee is as below.

CSR Committee: Deliberates on important matters concerning CSR, such as basic policies and overall strategy for the entire Kyowa Hakko Kirin Group.

Group Risk Management Committee: Deliberates on group-wide risk management, as well as the basic policy for the protection and handling of confidential information. Deliberates on basic compliance policies and ensures that compliance is maintained throughout the group.

Crisis Management Committee: Called by the Group Risk Management Committee as necessary if a crisis or a risk becomes apparent and requires immediate response occurs.

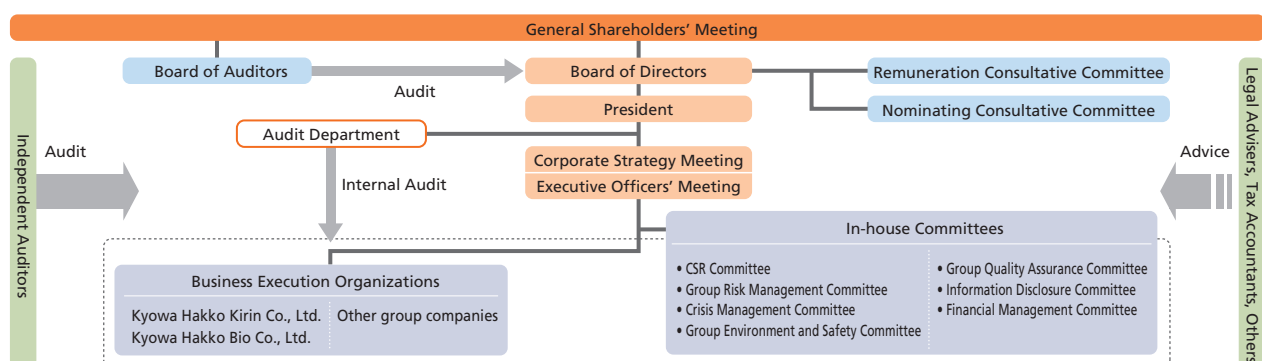
Group Environment and Safety Committee: An advisory group to the President that deliberates on basic policies relating to environmental conservation and safety.

Group Quality Assurance Committee: An advisory group to the President that deliberates on basic policies relating to quality assurance.

Information Disclosure Committee: Deliberates comprehensively on basic information policies and important matters relating to information disclosure.

Financial Management Committee: Deliberates on efficient financial activities and their accompanying risks.

Corporate governance organization



Risk Management and Compliance

In order to ensure systematic risk control, a Group Risk Management System is in place to identify risks that may affect our business activities and prevent serious ones from materializing. The situation is followed up every quarter or half-term. The system allows us to consistently work on preventing damage to customers and our business, and to take appropriate measures swiftly if any incident should occur. Based on the lessons learned from the Great East Japan Earthquake that occurred in March this year we are also reviewing our company-wide business continuity plan (BCP) and business continuity management (BCM) to ensure we are prepared in the event of a major earthquake directly under Tokyo or an outbreak of highly pathogenic influenza.

Promoting compliance in response to the demands of society is one of the fundamental requirements of CSR. At the Kyowa Hakko Kirin Group, compliance is promoted as a top priority issue in risk management. The CSR Committee determines the basic principles and policies regarding corporate ethics, and assists in the development of a "compliance mind-set" throughout the group.

Compliance education and awareness activities

To ensure that all group members are familiar with the Kyowa Hakko Kirin Group's compliance policy, we formulated the Kyowa Hakko Kirin Group Compliance Guidelines in March 2009. At Kyowa Hakko Kirin, a handbook summarizing the compliance required in the Pharmaceuticals business has been created and distributed to every employee. Furthermore, an education program comprising lectures, training, and e-learning is also provided annually to every employee to help them maintain high ethical standards at all times.

Corporate Ethics Lectures:

Lectures given by invited outside experts. The lectures are recorded on DVDs, which are available for viewing at every business site. [Corporate Ethics Lecture held in fiscal 2010]

Theme: *The Fiasco at Snow Brand Milk Products and the Road to Recovery*

Lecturer: Mr. Makoto Wakita, Director on the board, EN Otsuka Pharmaceutical Co., Ltd.



The 13th Corporate Ethics Lecture

Human Rights and Compliance Training: Training organized jointly by the Human Resources Department and the CSR Management Department. The training consists mainly of group work, and is designed to encourage participants to take part in various activities. The training even includes discussions on appropriate drinking habits, an important issue for the employees of a member of the Kirin Group, an alcoholic beverage manufacturer.

E-learning Instruction: A program centered on case studies. Ethics checks are also conducted during Corporate Ethics Month in October every year to allow employees to review their own day-to-day behavior.

Set up and operation of hotlines

The Kyowa Hakko Kirin Group maintains a number of hotlines that callers can use to make a report or seek advice in the event of discovering a legal or ethical violation or attempted violation. We are currently operating four hotlines, including an external one, that can be used not only by officers and permanent employees but also by temporary, part-time, and dispatched workers. We have also distributed small booklets and cards containing the contact information



A poster that reminds employees of the existence of the hotlines

to employees and regularly remind employees of the hotlines through the use of posters and during compliance training. The number of calls received during fiscal 2010 was 29 (compared to 23 in the nine months of fiscal 2009).

Ethical considerations in R&D

In its R&D on pharmaceuticals, Kyowa Hakko Kirin takes the following ethical considerations into account.

Bioethics: Kyowa Hakko Kirin sets internal rules with the aim of assuring ethical and scientific validity in human genome analysis and research using human tissue as well as preventing the loss of dignity and protecting the human rights of tissue donors.

Safeguarding human rights in clinical trials: When conducting a clinical trial involving human subjects, Kyowa Hakko Kirin observes the ethical principles contained in the Declaration of Helsinki, Good Clinical Practice (GCP: the standard to which clinical trials must conform), and related regulations (the Pharmaceuticals Affairs Act, etc.). We have also established internal rules consistent with GCP and the relevant regulations to make utmost efforts to protect human rights and maintain the safety of trial subjects (patients and volunteers).

Caring for laboratory animals: To ensure appropriate conduct in animal testing, a company-wide basic policy and specific experimental guide for each research site are established based on the Act on Welfare and Management of Animals and other laws as well as guidelines set out by the government and academic groups.

Our Aim is to Become a Pharmaceutical Company

Special Feature 1 **Kyowa Hakko Kirin**

For Patients the World Over

Global Specialty Pharma

ProStrakan Group plc

Kyowa Hakko Kirin Italia S.r.l.

Jeil-Kirin Pharm. Inc.

Kyowa Hakko Kirin Co., Ltd.

Kirin Kumpeng (China) Bio-Pharmaceutical Co., Ltd.

Kyowa Hakko Kirin (Taiwan) Co., Ltd.

Kyowa Hakko Kirin (Hong Kong) Co., Ltd.

Kyowa Hakko Kirin (Singapore) Pte. Ltd.

Europe

Realizing personalized medicine to meet the needs of every single patient

Dr. Gabriel Perez Cuevas
Senior Vice President,
Commercial- Southern Europe
ProStrakan Farmaceutica SLU



I have been recently appointed SVP Commercial-Southern Europe, as well as managing directly the business in Spain and Portugal. I'm proud of my team of highly skilled professionals who are self-motivated and committed to the future of our business. Our activities are focused on the development of new medicines to address unmet medical needs and we are working to enrich our portfolio of products in order to increase the therapeutic options available and realize personalized medicine that addresses the needs of every single patient.

We also would like to contribute to the development of health care by offering drugs with maximum safety and efficacy, donating medical products to and providing support for professional teams in developing countries, and meeting the needs of emergency disaster relief programs.

Topics Collaboration with the ProStrakan Group Plc

The ProStrakan Group, a company based in Scotland, the U.K., joined the Kyowa Hakko Kirin group in April this year. ProStrakan has an established development and marketing capability mainly for cancer-related drugs and has a track record for new drug approvals. Drawing upon their respective and complementary expertise, the two companies will work together to speed up the development and sales of new global drugs in the areas of focus.



Some of the ProStrakan staff

Asia

Meeting health care needs in the expanding Chinese market

Mr. Shen Weiqiang
Quality Management Senior Manager and
Production Planning Manager,
Production Division
Kirin Kumpeng (China)
Bio-Pharmaceutical Co., Ltd.



Rising incomes along with government health care reform efforts like the newly introduced health care program are leading more people in China to seek treatment at hospitals and driving the rapid expansion of the domestic pharmaceutical market. In addition, because the aging of the population is progressing at a fast pace, it is expected that the number of people needing health care will increase sharply.

In this rapidly growing pharmaceutical market, we local staff are working hard to develop products with high clinical value. We play an important role in reinforcing Kyowa Hakko Kirin as a global specialty pharmaceutical company.

Topics Establishment of Asian Development Department

Asian Development Department is developing drugs in the region stretching from Korea to India. With the aim of securing a steady supply of high-quality, high-value-added pharmaceuticals for China and other rapidly growing markets, we will participate in Multi-National Clinical Trials and the reinforce this new drug pipeline.



Asian Development Department

Leading Global Specialty

Kyowa Hakko Kirin undertakes R&D and sales of therapeutic antibodies and other new drugs created with its leading-edge biotechnology on a global scale.

Our aim is to become a leading global specialty pharmaceutical company and, by providing useful drugs, help as many patients as possible right across the world.

- : Major consolidated subsidiaries
- : Other subsidiaries

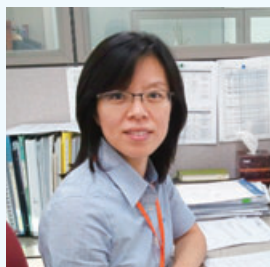


U.S.A.

Complementing our respective strengths in the immunology area

Developing human resources through joint clinical studies

Ms. Soo-Kyeong Park
General Manager,
R&D Department
Jeil-Kirin Pharm. Inc.



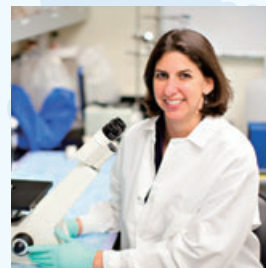
Pharmaceutical clinical studies approved by the authorities has recently been on the dramatic rise in Korea because of favorable circumstances surrounding clinical studies. Jeil-Kirin Pharm. (JK) is also placing a lot of focus on international joint clinical studies.

A member of Kyowa Hakko Kirin's clinical development team has joined JK's team since October 2010, and we think it can be a milestone in the employee exchange between KHK and JK to understand the mutual culture and to promote communication.

By taking part in joint multinational clinical studies, JK is building experience on the global studies and developing human resources etc.

Through these efforts, we can play an important role in contributing to the development of new drugs and to providing innovative drugs to patients suffering from uncured diseases.

Dr. Rachel Soloff
Associate Director
Research Division,
Immunobiology Group
Kyowa Hakko Kirin California, Inc. (KKC)



In 1998, Kyowa Hakko Kirin established a research lab in the same building as La Jolla Institute for Allergy and Immunology (LIAI) and started a collaborative Drug Discovery Program. The close communication and collaboration between the two organizations has resulted in the launch of many projects. The main areas of research at LIAI are autoimmunity, inflammation, and infectious diseases, and these areas complement Kyowa Hakko Kirin's focus areas of oncology, nephrology, and immunology. LIAI members engage in basic research, while projects undertaken by KKC and Kyowa Hakko Kirin translate the discoveries achieved in the basic research into cures for various human diseases. The ultimate shared goal of Kyowa Hakko Kirin and LIAI scientists is to address patient needs and improve their quality of life.

Topics Supporting the nonprofit research institute for many years

The La Jolla Institute for Allergy and Immunology is a nonprofit research institute established in La Jolla, California, the United States, in 1988, by Dr. Kimishige Ishizaka, an immunologist, to realize his aspiration of creating a world-leading research institute specialized in allergy and immunology. Kyowa Hakko Kirin shares this aspiration and has been working with the institute as a sponsor and partner for drug discovery and development.



The facility where LIAI and KKC work together

Developing Innovative Focusing on the Areas of and Immunology

R&D pipeline

Code name	Stage	Target disease
Oncology		
KW-0761*	Japan: NDA filed in Apr. 2011	Adult T-cell leukemia-lymphoma
	Japan: Phase II	Adult T-cell leukemia-lymphoma, Add-on therapy (for untreated patients)
	Japan: Phase II	Peripheral T/NK-cell lymphoma
	US: Phase I/II	Peripheral T-cell lymphoma and cutaneous T-cell lymphoma
KRN321 (NESP®) Darbepoetin Alfa	Japan: NDA filed in Nov. 2008	Chemotherapy induced anemia
KRN125 Pegfilgrastim	Taiwan, Vietnam: NDA filed	Chemotherapy induced febrile neutropenia
KW-2246 Fentanyl citrate	Japan: Phase III	Cancer pain
ARQ 197	Japan, Korea: Phase II	Gastric cancer
	Japan, Korea, Taiwan: Phase III	Lung cancer
KW-2478	UK, US, Philippines: Phase I/II	Multiple myeloma
KW-2450	US: Phase I/II	Cancer
KRN330*	US: Phase I/IIa	Cancer
BIW-8962*	US: Phase I/IIa	Cancer
KRN951	Japan: Phase I	Cancer
KHK2866*	US: Phase I	Cancer
LY2523355	Japan: Phase I	Cancer
Nephrology		
Cinacalcet Hydrochloride (REGPARA®)	Philippine, Malaysia, China: NDA filed	Secondary hyperparathyroidism
KRN321(NESP®) Darbepoetin Alfa	Japan: Phase III	Pediatric renal anemia
	India: Phase III/ China: Phase II	Renal anemia (on dialysis)
RTA 402	Japan: Phase I	Diabetic nephropathy
Immunology/allergy		
ASKP1240*	Japan: Phase I/ US: Phase II	Organ transplant rejection
Z-206 (ASACOL®) Mesalazine	Japan: Phase II	Crohn's disease
KHK4563* Benralizumab	Japan, Korea: Phase II	Asthma
Other		
AMG531 (ROMIPLATE®) Romiplostim	Singapore, Malaysia, Taiwan: NDA filed	Chronic idiopathic (immune) thrombocytopenic purpura
KW-6500	Japan: NDA filed	Parkinson's disease
KW-6002	Japan: Phase III/ US: NDA filed	Parkinson's disease
KW-6485 (TOPINA®)	Japan: Phase III	Pediatric epilepsy
KW-3357	Japan: Phase III/ Europe: Phase I	Disseminated intravascular coagulation, etc.
KHK6188	Japan: Phase I	Neuropathic pain
KRN23*	US: Phase I	Hypophosphatemic rickets

* Therapeutic antibodies

As of October 20, 2011

Oncology

Meeting the Challenges of Cancer Treatment through Antibody Technologies

The rare disease of adult T-cell leukemia-lymphoma (ATL)

Adult T-cell leukemia-lymphoma (ATL) is a viral disease that only develops in HTLV-1 (human T-lymphotropic virus type 1) carriers, of which there are many in Japan. However, only about 0.1% of the infected carriers, or 1,000 people each year, actually develop the disease. Once the disease manifests itself, the number of abnormal lymphocytes increases, the lymph nodes, liver and spleen become swollen, and red spots appear on the skin. Over time, the immune system also becomes weaker, making the patient prone to various diseases.

ATL is more common among middle-aged and older people, and is often fatal. It is difficult to effectively treat this disease with chemotherapy and apart from bone marrow transplantation no curative treatment has been established. Kyowa Hakko Kirin, however, has been working on the development of an therapeutic antibody that can help cure ATL.

NDA filed for an ATL-treatment therapeutic antibody developed in-house

On April 26, 2011, Kyowa Hakko Kirin submitted a new drug application (NDA) to the Ministry of Health, Labour and Welfare for KW-0761. KW-0761 is an antibody with enhanced ADCC (antibody-dependent cellular cytotoxicity) activity—a mechanism for killing cells and pathogens bound by antibodies—that exerts a controlling effect on CCR4, the antigen expressed on T cells, a type of lymphocytes. When the antibody binds to tumor cells, immune cells such as macrophages and NK cells subsequently bind to the antibody, which, exhibiting an antitumor effect, kills the ATL cells by way of its enhanced ADCC activity. KW-0761 is what is known as a humanized monoclonal antibody and has been created

New Drugs

Oncology, Nephrology,

Special Feature 1 **Kyowa Hakko Kirin**
For Patients the World Over
Global Specialty Pharma

Therapeutic antibodies eliminate viruses and other antigens by exploiting an innate human bodily response. Because antibodies find and attack only antigens, they are generally expected to have high efficacy with low side effects. Specializing in the areas of oncology, nephrology, and immunology, Kyowa Hakko Kirin is creating innovative new therapeutic antibodies.

by the application of POTELLIGENT®, a technology developed exclusively by Kyowa Hakko Kirin to produce antibodies with enhanced ADCC activity. The ADCC activity of KW-0761 is enhanced 100-fold compared to existing antibodies.

KW-0761 is the world's first POTELLIGENT® antibody submitted for marketing approval. The current NDA is seeking approval for the drug to be used on patients with relapsed CCR4-positive ATL following chemotherapy but we are also currently implementing clinical trials intended for untreated patients in which KW-0761 is combined with chemotherapy. We will continue this clinical development to ensure the drug's efficacy and safety.

Kyowa Medex

Companion diagnostics used to find cancer cells

On April 26, 2011, Kyowa Medex submitted a new drug application (NDA) to the Ministry of Health, Labour and Welfare for two *in vitro* diagnostic reagents. These reagents have been developed as companion diagnostics of the KW-0761 therapeutic antibody for ATL and are designed to be used for determining the presence of CCR4, the target antigen of KW-0761. Kyowa Medex and Kyowa Hakko Kirin started the joint development project for the reagents in 2009 and have already conducted clinical performance tests. The two reagents are used separately depending on where the cancer cells are: one is used on blood samples while the other is used on tissue samples from the lymph nodes or skin. Because the reagents make it possible to determine the existence of CCR4 expressed by ATL cells before administering KW-0761, treatment with the drug is expected to be more accurate and efficient than existing alternatives.

Voice of R&D staff

Developing a high efficacy anti-cancer drug that places a lighter burden on patients

During the clinical development of KW-0761, we were keenly aware of the high expectations of the doctors who were working with us on the clinical trials. In comparison with chemotherapy, which has strong side effects and places a substantial burden on patients, therapeutic antibodies are relatively mild. In addition to this, the KW-0761 antibody is enhanced with POTELLIGENT® technology and therefore has high efficacy. This means that patients can take a smaller dose of KW-0761 than they would need for existing therapeutic antibodies.

We have an earnest desire to find solutions for those suffering from cancer or leukemia and will continue working steadily toward this goal.

Hiroyasu Iwase

Clinical Development Department 1



Voice of R&D staff

Our mission is to deliver diagnostics that will lead to the early detection of cancer.

Tatsuya Shinoda

R&D Department, R&D Division



These companion diagnostics reagents are a first for both me and Kyowa Medex. Although we had to work incredibly hard every single day, because we belong to the same group we were able to share information and work together with Kyowa Hakko Kirin, which was a great help. The likelihood of curing cancer increases significantly if it is detected early. We will therefore continue to work hard to develop diagnostics for the early detection and efficient treatment of cancer by leveraging our antibody technology.

Nephrology

Developing Erythropoiesis Stimulating Agents that Can Be Used to Treat Both Children and Adults

Voice of R&D staff

Challenging work that has the potential to help many children suffering renal failure

When NESP® becomes available for children suffering renal anemia it is expected to eliminate the need for blood transfusions, alleviate anemia, and decrease the frequency of regular hospital visits. It is also reported that the drug will be effective in the treatment of malaise, anorexia, and declined learning volition and there are therefore high expectations for the drug among treating medical personnel. Many doctors



around the country are actively involved in the clinical trials and we often get requests directly from doctors and patients. Although the market is small, the development of a drug for children is challenging work and something we are very proud to do.

Takashi Murayama

Clinical Development Department 3

There are currently hundreds of thousands of adult chronic kidney disease patients in Japan, including those who are on dialysis. Conversely, chronic kidney disease in children is often hereditary and is very rare, with the number of patients in Japan totaling only in the several hundreds. The only curative treatment is renal transplantation, but because the chance of any given patient receiving a renal transplantation is quite limited, to control the symptoms of renal failure patients need to regularly undergo dialysis and frequently receive treatment for anemia caused by lowered renal function.

Kyowa Hakko Kirin developed ESPO®, a drug for renal anemia, when the company was still a department of Kirin Brewery and released it for both adult and child patients in 1990. In 2007, we developed NESP®, which features longer efficacy and can be taken less frequently than ESPO®. Clinical trials for NESP®, however, had only been conducted for adult renal anemia patients, meaning there was no established method of providing the drug safely to children. We therefore started clinical trials of NESP® aimed at child patients in October 2010 to verify its efficacy and safety.

Immunology

Pursuing Immune Disorder Drugs with Higher Efficacy and Less Side Effects

The number of patients suffering asthma, an immune disorder, is said to be about 900,000 in Japan. Asthma is characterized by airway inflammation and limited airflow, and symptoms include paroxysmal cough, wheezing, and dyspnea. In some cases, asthma can be fatal. Asthma can be treated with steroid inhalers that control inflammation and bronchodilators that stop paroxysms of coughing but in serious cases treatment with systemic steroids, which sometimes have associated side effects, may be necessary.

Eosinophils, lymphocytes, and mast cells, all of which are a type of white blood cells, are known to be involved in airway inflammation. Our KHK4563 treatment is designed to control eosinophils and thus works to relieve the symptoms of asthma. Therapeutic antibodies, such as KHK4563, are known to act on specific targets. The efficacy of KHK4563 is further potentiated by the use of Kyowa Hakko Kirin's proprietary POTELLIGENT® technology, which makes it possible for the drug to exert higher efficacy at a lower dose than other therapeutic antibodies. Phase 1 trial investigating its safety profile in healthy volunteers was completed and Phase II investigating efficacy in patients is currently under preparation.

Voice of R&D staff

Our aim is to deliver drugs as quickly as possible to patients suffering from disease.

When I talk to treating doctors and they tell me how many patients can be helped by the drugs we are developing I feel a renewed sense of motivation. If a person's immune system is too strong or too weak, that person can become ill. But if we can control the immune system to achieve optimum performance, it can work effectively against a wide variety of diseases. Although it will take some time before we can put KHK4563 on market, we will do our best to deliver this drug to patients suffering from asthma as quickly as possible.



Tadahiro Kakuno

Clinical Development Department 2

Maintaining the Lead in Fermentation Technology

Special Feature 2 **Kyowa Hakko Bio**
For Human Health

In 1956, Kyowa Hakko Bio (formerly Kyowa Hakko Kogyo) developed the process of amino acid production by fermentation for the first time in the world. Ever since, the company has been producing and supplying amino acids and various other beneficial substances for use as raw materials in health foods, cosmetics, medical infusions, and other products. We will continue contributing to human health through fermentation technology.

R&D

Exploring the potential of microorganisms

I'm tasked with developing microorganisms that can be applied to produce beneficial substances for use as raw materials for pharmaceuticals and foods, as well as with creating the production processes. Two years ago, we began working on the development of a fermentation production method for *cis*-4-hydroxy-L-proline, a kind of amino acid that is believed to have potential as a raw material for pharmaceuticals. We are now the first in the world to successfully launch commercial production of the substance. In the development process we consulted a good many experts and are very proud of our results. Fermentation enables us to produce beneficial substances more efficiently and with less environmental impact than chemical synthesis. I will continue my research to further exploit the potential of microorganisms and hope to help create more beneficial substances.



Shihomi Imamura

Technical Research Laboratories,
Yamaguchi Production Center

Product
development,
marketing

Developing products that people need



Koichiro Miyake

Manager, Marketing & Business
Development Dept.

My job is to monitor market needs through market research and customer visits and make fitting proposals for the development of new materials as well as to explore new applications and find new value in existing materials developed using Kyowa Hakko Bio's fermentation technology.

As well as being important nutrients and building blocks of the body, amino acids can be used in various applications including as raw materials for pharmaceuticals, foods, cosmetics, and supplements. They are compounds that are indispensable for maintaining health and improving the quality of life. Contained in infusions used at medical institutions, amino acids provide patients with an essential nutritional supplement. Amino acids are also expected to play an important role in efforts to address such issues as aging population and need for a steady food supply.

Production,
quality
assurance

Ensuring safety and a steady supply of products

The manufacturing staff conduct the fermentation and purification of amino acids and nucleic acids according to processes developed at the Technical Research Laboratories so that they can be supplied as products for use in pharmaceuticals, foods, and cosmetics. As a member of the manufacturing support staff, I'm involved in a wide range of operations including the installation and management of machinery, process management, and environmental safety. For each complex process we also need to check the quality of the microorganisms and raw materials used for manufacturing and monitor pH, temperature, concentration, and many other values to ensure that they do not deviate from the strictly defined standards, all the while striving to maintain a steady supply of highly safe and pure products. We also actively seek out opinions and suggestions from the line personnel in order to make continuous improvements to the facilities.



Kenichiro Ago

Manufacturing, Yamaguchi
Production Center

Supplying Superior Products through a Stringent Quality Assurance System

Dedication to Product Safety and Quality Assurance

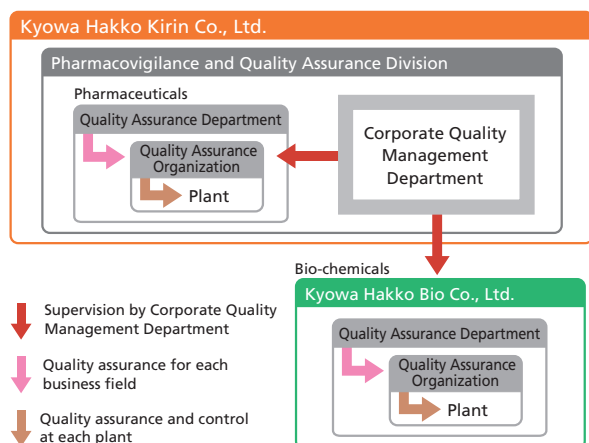
The Kyowa Hakko Kirin Group divides its business activities into two fields: Pharmaceuticals and Bio-chemicals.*1 In each of these fields, sound operation of the quality assurance system is ensured by way of our three-layered system. The first layer is a quality assurance organization at each plant. Further up, we have quality assurance organizations overseeing each of the two fields of business. Finally, we have the Corporate Quality Management Department, which is responsible for supervising the quality assurance activities of the entire group. In all of our quality assurance activities, we ensure regulatory compliance and make the safety of our customers our number one priority.

*1 See pages 7 and 8 for details.

Quality Assurance Policy of the Kyowa Hakko Kirin Group

- We maintain a high level of quality and provide products and services that achieve customer satisfaction.
- Safety is our first priority. We provide products and services that gain the trust of customers through the reliable Quality Assurance System in compliance with applicable laws and regulations.

The Kyowa Hakko Kirin Group's quality assurance organization



Quality assurance in the development of pharmaceuticals

In the development of pharmaceuticals, manufacturers are required to ensure the reliability of application data and protect the safety and human rights of the people who participate in clinical trials by fully complying with the Good Laboratory

Practice (GLP),*2 Good Clinical Practice (GCP),*3 and the Criteria for the Reliability of Application Data. At Kyowa Hakko Kirin, we have established Pharmaceutical Development Guidelines and Standard Operating Procedures (SOP) to meet these standards, as well as the Global Company Quality Assurance Policy. Under these governing documents, we strive to assure and maintain reliability throughout the entire R&D process for new drugs, from preclinical studies to human trials.

*2 **Good Laboratory Practice (GLP)**: Standard for the conduct of nonclinical laboratory studies for pharmaceuticals

*3 **Good Clinical Practice (GCP)**: Standard for the conduct of clinical trials for pharmaceuticals

Manufacturing control and quality control of pharmaceuticals

To ensure the high quality of our pharmaceuticals, we periodically audit the manufacturers in Japan and overseas that perform our outsourced production, as well as our own plants. Our auditors visit the plants to confirm that they are upholding the Good Manufacturing Practice



Quality control of pharmaceuticals

(GMP)*4 with regard to manufacturing control and quality control and that they are complying with both the Pharmaceutical Affairs Act and the Quality Agreements. In the event that our auditors determine improvements are needed, we provide the necessary instructions. At other times, if a serious problem occurs in connection with the manufacturing, we immediately send investigators to the plant to identify the cause and take action to prevent recurrence.

*4 **Good Manufacturing Practice (GMP)**: International standard governing the manufacturing control and quality control of pharmaceuticals

Recall of COBAMYDE tablets

In the summer of 2010, we recalled our vitamin B12 supplement COBAMYDE 500 µg tablets. We would like to express our deepest apologies to both patients and health care professionals for the concern and inconvenience caused by this recall. The recall was necessary as the vitamin content of the tablets had decreased over time. Although the efficacy of the tablets is weak, they neither present associated safety concerns nor cause adverse effects. We will make our utmost efforts to apply even more stringent quality control to our products.

Maintaining the safety of pharmaceuticals

For pharmaceuticals to be used safely and effectively, it is important that health care professionals are provided with comprehensive safety information. To ensure this, we gather data from doctors, pharmacists, and patients as well as from literatures published, medical societies, and regulatory authorities in and outside Japan. All of this data is analyzed and evaluated and important findings are reported directly to health care professionals by medical representatives (MRs)*⁵ and via the company's website.

*⁵ **Medical representatives:** Personnel who gather data from, and provide useful information to, health care professionals

Quality assurance in Bio-chemicals

Amino acids and other fermentation products offered by Kyowa Hakko Bio are used in a wide range of applications, such as pharmaceuticals, foods, food additives, health foods, cosmetics, and pharmaceutical synthetic intermediates. Our products are manufactured in plants in Japan, the United States, and China and supplied to markets around the world.

To ensure the safety of our products, production processes and quality are strictly controlled in accordance with the Good Manufacturing Practice (GMP) for pharmaceuticals.

Communication with Customers

Sharing useful information on the Web

Kyowa Hakko Kirin's websites serve as an important source of information for patients. Our Antibody Technology site, for example, uses illustrations and video to explain what therapeutic antibodies are and how they differ from low molecular drugs.

Our Chronic Kidney Disease (CKD) site offers basic information about CKD, Q&As on CKD, cartoons that help explain CKD, a self health check, and various other sections that stress the importance of early detection and early treatment of the disease.

Medical Information Office

The main task of our Medical Information Office is to respond to inquiries about our products from health care professionals and patients and their families. The number of inquiries received last fiscal year exceeded 33,000.

The office also shares information it gathers in the course of answering inquiries with relevant departments within the company and works with them as necessary to provide product safety and quality information to medical institutions.



The Medical Information Office

Development of ALLELOCK®

Since its release in 2001, ALLELOCK® has been one of the most effective options for patients suffering from allergies.

In July 2010, the normal tablet and orally disintegrating (OD) tablet*⁶ versions of the product received additional approval for use by children aged seven and older. In addition, the granular form released in November 2011 was approved for use by children aged two and older. To make it

more palatable to children, the granular form of ALLELOCK® is sweetened. Similarly, the OD tablets disintegrate quickly in the mouth and so can be taken without water, making them particularly suitable for small children and elderly people who have difficulty swallowing.

We will continue our efforts to develop products that provide real benefits to patients and their families.



*⁶ **Orally disintegrating (OD) tablets:** Tablets developed using our latest technology. They have the hardness of normal tablets but disintegrate quickly when placed in the mouth.

Pursuing Management with Integrity and Transparency while Promoting Proper Information Disclosure

Basic Policy Regarding Information Disclosure

The Kyowa Hakko Kirin Group regards investor relations (IR) as an important management issue and endeavors to provide shareholders and investors with information in a manner that is timely, appropriate, and fair. We have formulated our disclosure policy to help shareholders and other investors understand the group and to ensure the integrity and transparency of management.

Basic Disclosure Policy

Based on the principles of transparency, fairness, and consistency, Kyowa Hakko Kirin strives to provide timely, accurate disclosure of information to shareholders and other investors in accordance with the Financial Instruments and Exchange Act and the timely disclosure rules of the Tokyo Stock Exchange (TSE). In addition, Kyowa Hakko Kirin is committed to the timely, active disclosure of other information that, in the judgment of the Company, will be effective in helping shareholders and other investors to understand Kyowa Hakko Kirin.

Audio recordings and presentation materials are available on the Kyowa Hakko Kirin IR website for those unable to attend.



Annual Results Presentation Meeting (January 28, 2011)

Publication of "To Our Shareholders" and annual report

We publish a business report, "To Our Shareholders," twice a year, and send it directly to shareholders. We also distribute printed English-language annual reports to overseas investors. These two publications, as well as our Japanese-language annual reports, are also available on our IR website.



Business report "To Our Shareholders"

web English Investor relations (IR) website:
<http://www.kyowa-kirin.co.jp/english/ir/index.html>

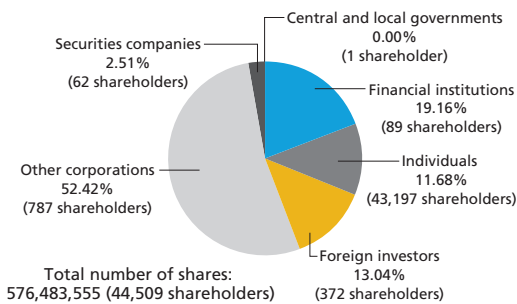
Listing on socially responsible investment (SRI) index

Kyowa Hakko Kirin is included on one of the world's major socially responsible investment indexes, the FTSE4Good Index Series.



FTSE4Good

Shareholder composition (as of December 31, 2010)



Communication with Shareholders and Investors

Results Presentation Meetings

Twice a year, following the announcements of interim and year-end financial results, Kyowa Hakko Kirin holds meetings at which the President and other senior management members explain its business results and management policies to institutional investors and securities analysts.

Sale of shares of Kyowa Hakko Chemical

Kyowa Hakko Kirin sold all shares held in Kyowa Hakko Chemical Co., Ltd. to KJ Holdings Inc. on March 31, 2011. This enables Kyowa Hakko Kirin to efficiently focus its resources on its ethical pharmaceutical products business and allows Kyowa Hakko Chemical to flexibly implement the capital expenditure required to meet diverse market needs. We will continue our efforts to solidify our business foundation in order to achieve sustained growth.

Building a Fulfilling Work Environment where Employee Diversity Is Valued

Kyowa Hakko Kirin's Human Resources (HR) Philosophy

Kyowa Hakko Kirin has established an HR Philosophy, a set of basic principles concerning human resources that will help us develop a professional workforce capable of achieving the company's vision to become a "global specialty pharmaceutical company" and promoting and embodying the ideas set out in "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin."^{*1} The HR Philosophy is the foundation of our HR policies and the corporate culture of Kyowa Hakko Kirin. Based on its principles, personnel are expected to pursue our strategies.

*1 See page 6 for the full text.

Kyowa Hakko Kirin's HR Philosophy

We value employees' self-initiative, encourage them to improve their abilities and creativeness, and will create a work environment in which they can pursue their own infinite possibilities and be fully motivated at work.

- **Developing professionals**
We will provide employees with opportunities where they can proactively seek new challenges to acquire high expertise and a broad vision.
- **Promoting diversity**
We will provide employees with opportunities where diverse human resources can work well together by understanding and respecting different values.
- **Clarification of mission and fair treatment**
We will share the company's vision and goals with employees to continuously enrich the value of their work, and clarify their expected roles.
We will evaluate and reward employees fairly for their achievements and contributions to the company.

(Established in March 2009)

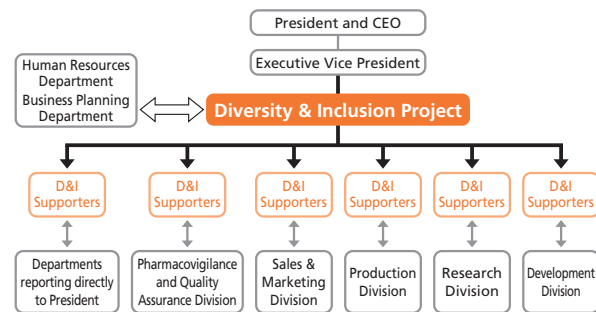
Creating a Lively Work Environment

Promoting diversity and inclusion

Kyowa Hakko Kirin is pursuing the development of a work environment that encourages employees to live up to their full potential and fully express their individuality. One example of such efforts is the Diversity & Inclusion Project (D&I PJ), a cross-company project launched in October 2010. As the first stage

of this project, in fiscal 2011, we are promoting activities aimed at creating a corporate culture in which gender presents no barrier to any employee seeking to further their career. More specifically, we are currently working on (1) enhancing employees' understanding of diversity and inclusion; (2) introducing role models via the company's intranet; (3) providing opportunities for communication among employees; and (4) exploring new work styles. In the future, we will actively progress activities under the D&I PJ to foster a motivational culture that bolsters all employees.

Diversity & Inclusion Project organization



Promotion of human rights

Kyowa Hakko Kirin conducts activities to promote human rights based on the policies and measures determined by the Kirin Group Human Rights Promotion Committee.^{*2} One such activity is the Human Rights Training Program launched in 2009 targeting all employees. This program has also been introduced to Kyowa Hakko Bio, Kyowa Medex, and other Kyowa Hakko Kirin Group companies to enhance employee awareness of the importance of human rights throughout the group.

Other human rights promotion activities include conducting surveys on the human rights awareness of our employees in conjunction with other companies belonging to the Kirin Group; conveying a message from the President to employees during Harassment Elimination Month; and soliciting slogans from employees for Human Rights Week. We have also established hotlines that employees can call to report or seek advice on harassment and other human rights issues.

^{*2} **Kirin Group Human Rights Promotion Committee:** A committee chaired by the human resources director of Kirin Holdings and staffed by human resources department managers from the major companies within the Kirin Group

Childcare Support Policy

To create a work environment where every employee can pursue their full range of career options regardless of their lifestyle or gender, Kyowa Hakko Kirin is promoting childcare support based on the following concepts in cooperation with the labor union.

Kyowa Hakko Kirin Childcare Support Policy

- We recognize that the creation of a society and companies that provide equal opportunities for men and women is an important matter to Kyowa Hakko Kirin and will support that effort.
- We support employees who require temporary leave or workload reduction for taking care of their children, but wish to continue employment and grow with the company.
- We seek to develop a group-wide culture of supporting employees involved in childcare by instilling awareness that the reconciliation of work and childcare is beneficial to Kyowa Hakko Kirin, while encouraging employees who receive support to actively seek harmony with their fellow employees.

Childcare support measures

At Kyowa Hakko Kirin, employees can take time off until their child reaches two years old. In addition, mothers and fathers can choose to work shorter hours for a total of up to 48 months*1 at any time until their child completes the third grade of elementary school. In fiscal 2010, the total number of employees who took childcare leave was 113 while around 50 employees per month worked shorter hours.

*1 The total number of months in which employees can take childcare leave and/or work shorter hours

Employment of people with disabilities

Kyowa Hakko Kirin is actively providing employment for people with disabilities. As of the end of December 2010, we employ 78 workers with disabilities. This constitutes 1.7% of our total workforce, which falls short of the statutory requirement of 1.8%. We are currently making every effort to increase the rate for the next fiscal year and thereafter.

We are also working hard to help people with intellectual disabilities find jobs by offering work experience programs*2 to students of designated Tokyo Metropolitan Special Support School.*3 Seeking to help create a society in which everyone can work and live



Work experience program

in harmony, we will continue our efforts to promote diversity and develop workplaces where everyone, regardless of ability or disability, can engage in meaningful employment.

*2 **Work experience programs:** On-the-job training that includes computer-based data entry, filing, collection and delivery of mail, and copier paper replenishing

*3 **Tokyo Metropolitan Special Support School:** Schools that offer, as part of their high school program, a *Shugyo Gijutsu-ka* (vocational course) that prepares intellectually disabled students for work in the private sector

Development of Human Resources

Independent career development

As stated in its HR Philosophy, Kyowa Hakko Kirin respects the independence of each employee and pledges to “encourage them to improve their abilities and exhibit creativeness, and create a work environment in which they can explore their own infinite possibilities and feel a strong motivation to work.” To fulfill this commitment, we offer various tools and training programs to encourage voluntary career development.

● Career Development Sheet

This tool helps employees create mid- to long-term concrete career plans. Each employee also meets with his or her immediate supervisor to seek advice and make sure that their career plans are aligned with the company’s career development policy.

● Career Life Design Seminar (CLDS)

The objective of this seminar is to encourage employees to look back over their career and life and consider their future in the light of their personal values and goals. Upon completing the seminar, employees are given special leave to give careful thought to their future plans.

● Optional training programs

Training programs featuring a variety of modules from which employees can choose on their own to enhance their skill set and broaden their perspective.

● **Self-development support system**

A system to support employees actively pursuing their own professional development by subsidizing fees for external training programs

Development of a globalized workforce

As Kyowa Hakko Kirin further embraces globalization, we urgently need employees who can achieve results in international settings. To meet this need we have introduced various training programs.

The optional training programs offer a variety of modules that provides employees with an opportunity to obtain the skills and mindset needed to work overseas. In addition, the Kyowa Hakko Kirin School (KHK School), which runs longer courses, offers the Global Management Program targeting Japanese employees. The objective of this program is to develop effective expatriate employees and international representatives who can perform equally well in both the international arena and Japan. Employees undertaking this English-language program learn business skills and develop the global mindset necessary for building trust with overseas partners.

The school also runs a Global Executive Program that prepares candidates to undertake senior management positions in various countries. The program is open to executive candidates from overseas subsidiaries as well as managers in Japan, and provides training in major business school subjects and the various management skills needed to work at the executive level. Upon finishing the program, trainees have the ability to formulate and implement strategies and conduct daily operations as an

executive in a global environment.

In addition to these programs, fee subsidies for external language education programs are available under the self-development support system. TOEIC (Test of English for International Communication) IP (Institutional Program) tests are also implemented within the company.

voice

The program reminded me of the importance of having a vision.

Dae-Man Hwang
Senior Product Manager
Hemato-Oncology Team
Strategic Product Planning Department
Jeil-Kirin Pharmaceutical Inc.



My participation in the Global Executive Program made me think back to when I first started working as a medical representative (MR) and helped renew my determination and motivation for what I do. Through this program, I realized for the first time how important it is for companies to have a vision as well as the true meaning of the “value of life,” as stressed in Kyowa Hakko Kirin’s vision. In the past I am no doubt guilty of having carelessly hurt other people’s feelings or caused offense. But from now on, together with my colleagues and others, I will work even harder in the service of this precious thing we call life.

The Kyowa Hakko Kirin Group training programs (fiscal 2011)

	Compulsory training programs	Optional training programs			KHK School
Managers	<ul style="list-style-type: none"> CLDS (II for managers) CLDS (I for managers) New Manager Training 	<ul style="list-style-type: none"> Corporate Strategy Accounting Basics for Managers (Accounting & Finance) 	<ul style="list-style-type: none"> Global Mindset Reading English Contracts Negotiation 	<ul style="list-style-type: none"> Coaching for Managers Leadership for Managers 	<ul style="list-style-type: none"> KHK Corporate Management Seminar II Global Executive Program
Non-managers	<ul style="list-style-type: none"> CLDS (III) CLDS (II) CLDS (I) Second-year Employee Follow-up Training New Employee Training 	<ul style="list-style-type: none"> Pharmaceutical Business Strategy Marketing Strategy for Life Science Business Accounting Basics (Accounting & Finance) 	<ul style="list-style-type: none"> Business Meeting Business Presentation Logical Communication in English E-mail Writing How to Receive Telephone Calls in English 	<ul style="list-style-type: none"> Coaching Facilitation Leadership Followership Persuasive Communication Identifying and Solving Problems Followership 	<ul style="list-style-type: none"> KHK Corporate Management Seminar I Global Management Program Strategy for Pharmaceuticals

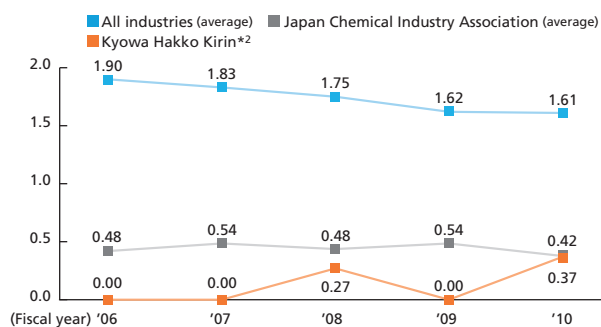
Note: The training courses in are open to both managers and non-managers.

Ensuring Workplace Safety

Occupational safety and health

To prevent industrial accidents, the Kyowa Hakko Kirin Group conducts risk assessments at each business site as part of its daily production activities and prior to construction work. These assessments are based on the group's environment and safety policy, which is revised each year. We are also working toward establishing a group safety training program to promote safety awareness among employees. The progress of safety activities is checked in the annual safety audit, and the audit results are reported to management at a meeting of the Environment and Safety Committee and reflected in the action plan for the following year.

Accident frequency rate*1



*1 The number of fatal and lost time accidents per million working hours
 *2 Including Kyowa Hakko Bio, Kyowa Hakko Chemical, and Kyowa Medex

In fiscal 2010, the number of accidents resulting in lost work time at Kyowa Hakko Kirin, Kyowa Hakko Bio, Kyowa Hakko Chemical, and Kyowa Medex was two. Both the accident frequency rate and the accident severity rate*3 were low at 0.37 and 0.0005, respectively. Details of accidents and measures taken are shared throughout the group to prevent recurrence.

*3 The number of lost days per 1,000 working hours

New manager training

We provide training to newly appointed managers at the group's plants and laboratories on important environment and safety management issues such as the group's environment and safety policies and safety education. This training covers all the matters that newly appointed "safety officers" as defined in the Industrial Safety and Health Act are required to learn.

Traffic safety promotion

Kyowa Hakko Kirin has a fleet of approximately 1,500 vehicles for use by salespeople in the field. To maintain high safety awareness among our salespeople, we introduced a traffic safety training program in fiscal 2008. For new employees, we perform a unique five-scale assessment of their driving skills to help them enhance their driving techniques and safety awareness. Furthermore, as part of measures to prevent accidents, we also conduct hazard prediction training by installing driving recorders.

Awards

As in past years, we again received a number of awards in fiscal 2010 for our efforts relating to product safety, quality control, information disclosure, environmental protection, safety and health, and other matters. The table below shows the major awards received.

Kyowa Hakko Kirin	Japan Institute of Information Technology "IT Management Award" (Head Office Information System Department)
	Nagaizumi Fire Chief Award for Business Sites Achieving Excellence in Fire Prevention (Fuji Plant, Fuji Research Park)
	Type 4 Zero-Accident Record Certificate (formulation and production of pharmaceuticals and bulk pharmaceuticals) (Fuji Plant, Fuji Research Park)
	Gunma Pharmaceutical Industry Association "Distinguished Service Award" (Hideaki Takahashi, Takasaki Plant)
Kyowa Hakko Bio	Yamaguchi Prefecture Green Curtain Contest "Excellence Award" (Yamaguchi Production Center)
	Minister of Health, Labour and Welfare Award for Foremen with an Outstanding Record of Implementing Safety Activities (Shunichi Ishijima, Tsukuba Development Center)
Jeil-Kirin Pharm. Inc.	Appreciation plaque from Korea Blood Cancer Association
	Commendation and appreciation plaque from the Korea Marrow Donor Program

Creating safe workplaces where everyone can work comfortably

Shunichi Ishijima

Administration Group
 Tsukuba Development Center
 Kyowa Hakko Bio



Since its establishment in 1989, the Tsukuba Development Center has maintained its zero-accident record thanks to our predecessors' tremendous efforts to continually improve safety. We have established a system that encourages everyone to take part in workplace patrols, provide health and safety alerts over the public address system, and perform other safety activities on a rotating basis to enhance employee safety awareness. I'm honored to have received the "Fiscal 2010 Minister of Health, Labour and Welfare Award for Foremen with an Outstanding Record of Implementing Safety Activities." I will continue carrying out my duty as a supervisor with the aim of creating an even safer workplace where everyone can work comfortably.

Building a Stronger Connection with Society as a Corporate Citizen

Ensuring the Safety of Communities

Disaster response system

Under the Kyowa Hakko Kirin Group's disaster management system, a Safety Measures Headquarters headed by an executive manager will be established immediately in the event of a business site being damaged in an explosion, fire, earthquake, or any kind of natural disaster to provide support for rescue and recovery activities. Each business site regularly performs risk assessments and other disaster response activities, puts in place a number of disaster preparation and mitigation measures, and periodically conducts disaster preparedness drills.

Measures to prepare for a major earthquake

To meet its social responsibility as a manufacturer—particularly as a supplier of pharmaceuticals that are urgently needed in disaster situations—the Kyowa Hakko Kirin Group has progressively taken measures against possible emergency scenarios since the 1970s, when the possibility of an earthquake in the Tokai region was first suggested. These measures include developing regulations, dispersing production and distribution operations, earthquake-proofing buildings, and installing handheld satellite phones at each business site including sales offices.

When the Great East Japan Earthquake occurred on March 11, 2011, we set up the disaster control headquarters immediately and, under its direction, checked the safety of each employee and started recovery activities for affected business sites. Because the contracted manufacturers to which we had outsourced production of some of our products were damaged, making production and shipment from these factories extremely difficult, we made the decision to move production of those products to our own plants in order to quickly restore a stable supply.

From the experiences of the earthquake we identified various improvement points, such as the function of the radio communication system used to check the safety of employees and the way handheld satellite phones are operated. Based on the lessons learned, we will continuously review and reinforce our business continuity plan (BCP).

Disaster preparedness drills

We periodically conduct practical disaster preparedness drills at all group business sites to raise disaster awareness among employees.

At the Head Office, a drill aimed specifically at verifying our IT BCP, as well as a regular general disaster drill, was conducted

in fiscal 2010 to confirm the effectiveness of the process for restoring the IT system following an earthquake.

At our plants, in addition to disaster drills conducted in cooperation with fire stations, automated external defibrillator (AED) drills, fire extinguisher drills, and water discharge drills are carried out.

Inappropriate management of transgenic mice

Kyowa Hakko Kirin has been conducting research activities in accordance with internal rules, which were established based on the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms. However, in August 2010, it was discovered that the number of transgenic mice actually kept at the Tokyo Research Park did not match the number recorded.

We would like to express our sincere apologies to neighboring residents and the many other persons affected for any concern caused.

The Tokyo Research Park immediately suspended all experiments involving transgenic animals, reviewed the Standard Operating Procedures (SOP), and reinforced the check system to ensure stricter management of the animals and prevent the recurrence of a similar incident. Furthermore, because the initial response to the incident was not prompt enough, we redesigned our reporting and communication system to enable us to take appropriate action more swiftly in the event of a problem occurring. We also educated employees about how to deal with unexpected incidents and conducted emergency response training. Only after confirming that each of these countermeasures was being properly implemented by employees did we decide to resume experiments in February 2011.

We take this incident very seriously and will keep a close eye on research activities as well as other activities so as to maintain the public trust.

Communication Activities in Japan

Distribution of free braille calendars

Each year since 1994, we have produced braille calendars for people with visual impairments and distributed them free of charge to schools for the blind nationwide. We delivered 4,011 copies of the 2011 calendar to 71 schools.



2011 braille calendar

Responsible Care Community Dialogue

Kyowa Hakko Bio participates in community dialogue activities promoted by the Japan Responsible Care Council (JRCC). For example, the company's Yamaguchi Production Center and three other JRCC members host a Responsible Care (RC) Community Dialogue meeting every year in the Ube area. The meeting held in February 2011 attracted about 70 attendees, including local residents as well as representatives from environmental NGOs, local governments, and local companies. Following a tour of the Ube Chemical Factory belonging to Ube Industries, Ltd. and presentations by each JRCC member company on their environmental efforts, the participating companies and attendees held discussions on such issues as the "management of chemical substances" and "factories and community development," and reaffirmed the importance of collaboration among industry, government, academia, and citizens to overcome problems facing the community.



Ube area RC Community Dialogue meeting

Tours of plants and laboratories

We organize tours of the plants and laboratories belonging to the Kyowa Hakko Kirin Group for the purpose of promoting communication with local residents and enhancing their understanding of the group's business.

To improve understanding of pharmaceutical production the Fuji Plant and Fuji Research Park hold a tour of their drug formulation site, including screening a video that explains plant operations. These sites also hold an annual Health Promotion Lecture to provide health care tips to local adults. The fiscal 2010 lecture, titled "Foods that will Help You Look Young and Beautiful," attracted around 85 people.



Health Promotion Lecture

The Tokyo Research Park organizes lectures on its latest technologies and site tours for students, group companies, government agencies, and others. Nine such lectures and tours were held in fiscal 2010.

Kyowa Hakko Bio's Yamaguchi Production Center invited 30 elementary school teachers from Hofu City to tour its premises as part of social studies training for teachers planned by the Hofu City Elementary Education Study Group.

Children's science experiment classes and the bio-adventure project

We offer science experiment classes at our plants and laboratories to create opportunities to share the excitement of science with large numbers of children. Furthermore, the research staff at the Tokyo Research Park have been taking the Bio-adventure vehicle to local elementary and junior and senior high schools since 2000 on a volunteer basis to carry out science experiments involving genes, microbes, and other subjects. The Bio-adventure vehicle is a special vehicle equipped with microscopes and other necessary instruments. In fiscal 2010, the staff visited six schools and helped instill a total of 194 children with an interest in science.



The Bio-adventure vehicle



Science experiment class

Kyowa Hakko Kirin table tennis meet

The Kyowa Hakko Kirin Table Tennis Club, which is involved in various activities to promote human health and well-being through table tennis, hosted a table tennis meet at the Tokyo Metropolitan Gymnasium on March 2, 2010 in cooperation with other Kirin Group and Kyowa Hakko Kirin Group companies and other companies involved in the table tennis sector. Under the theme of "Table Tennis Fun Day," the meet attracted 420 participants, who were offered table tennis lessons and opportunities to take photographs with, shake hands with and get autographs from club players. Both the club players and participants had a good time. A total of 49,960 yen in lesson fees collected on the day were donated to support Haiti's earthquake recovery.

Upon requests from the Ministry of Education, Culture, Sports, Science and Technology, the Table Tennis Club players also visit elementary schools to help children discover the fun of the game.



Kyowa Hakko Kirin table tennis meet

The Kato Memorial Bioscience Foundation

The Kato Memorial Bioscience Foundation was established in 1988 for the purpose of promoting bioscience research in Japan. The foundation offers grants to scientists who are conducting prominent creative research in the bioscience field, as well as financial aid to support international exchange and help scientists organize conferences. In fiscal 2010, the foundation provided grants for 25 research projects, 31 international exchanges, and 10 conferences in the medical science and biotechnology fields.



Special lecture at a research grant awards ceremony

web The Kato Memorial Bioscience Foundation
<http://www.katoken.or.jp/>

Communication Activities outside Japan

Donation of drugs to the 2010 Pakistan floods

The northwestern area of Pakistan was flooded by record-breaking rainfall from the end of July to the beginning of August 2010. To help save lives in the region, we responded to a request from the Pakistan Embassy in Tokyo to support relief activities by donating 965,000 capsules of PASETOCIN® Capsules 250, a synthetic penicillin (antibiotic) preparation, to the Pakistan government in September with the cooperation of the Japan Pharmaceutical Manufacturers Association (JPMA).

Donation of medical instruments and a stable supply of pharmaceuticals to developing countries

In developing countries where many counterfeit or substandard medicines are traded and consumed, the improvement of drug quality is urgently needed. For years now, Kyowa Hakko Kirin has been donating high-performance liquid chromatographs (HPLCs) to the Cambodian Ministry of Health, the Laos Pharmaceutical Development Center, the Thai Ministry of Public Health, and other organizations via the Japan Pharmaceutical Manufacturers Association (JPMA) to help them analyze the ingredients of medicines by themselves. Furthermore, the JPMA is working together with Kanazawa University on a project to combat

counterfeit medicines in Cambodia and one of our HPLCs was donated to Kanazawa University via JPMA for sample analysis in May 2010.

Since the 1970s, we have also been providing a steady supply of LEUNASE Injection, a medicine indispensable in the treatment of pediatric hematological malignancies, to developing countries in Asia, contributing to the medical care of children who suffer from the disease. In addition to developing countries in the Asian region, this medicine is supplied all over the world including Europe.

Joining the Seoul Citizen Marathon to help pediatric patients with cancer

“Run for others at least one day a year!”—this is the slogan of the Seoul Citizen Marathon, an event organized in Seoul every year to help pediatric patients with cancer. The objective of the event is to become a beacon of hope for children whose days, through no fault of their own, are tainted by the suffering of the disease, rather than filled with dreams and hope. In 2010, the event was held on May 2, with 70 employees of Jeil-Kirin Pharm. Inc. and their families taking part. A total of 1.5 million won was raised, all of which was donated to support the care of socially and financially disadvantaged childhood cancer patients.



Seoul Citizen Marathon

Spend a day in a childcare center campaign

In Seoul, people are encouraged to work in a childcare center on the fourth Saturday every month to take care of infants less than six months of age. The campaign also seeks financial support for the families of children with physical disabilities and premature babies needing surgery and long hospital stays. The same campaign also urges people to act as short-term foster parents to parentless infants until long-term arrangements can be made. In fiscal 2010, a total of 122 staff from Jeil-Kirin Pharm. Inc. and their families participated in this campaign.



Spend a day in a childcare center campaign

Implementing and Continuously Improving Management Systems

Environmental and Safety Management

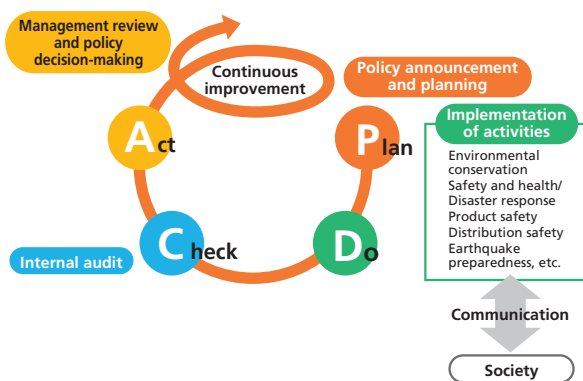
The Kyowa Hakko Kirin Group has in place both an ISO 14001-accredited environmental management system and an occupational safety and health management system centered on risk assessment, and continuously improves them through a systematic Plan-Do-Check-Act (PDCA) cycle. Our environmental and safety activities are based not only on the relevant laws and regulations but on additional, more rigorous targets that we have voluntarily imposed on ourselves. We will continue our environmental activities under the ISO 14001 management system to achieve our goal of low carbon corporate operations right across the supply chain.

Basic Policy on the Environment, Safety, and Product Safety

Based on the Kyowa Hakko Kirin Group Management Philosophy, we will exert ourselves to realize an affluent society by conducting business activities with scientific consideration for health, safety, the environment, and product safety throughout the entire life cycle of each of our products. That extends from research and development through production, marketing, use, and disposal. At the same time, we are making efforts to ensure the quality and safety of our products, taking the safety of consumers as a matter of the greatest importance.

(Established October 1, 2008)

Environmental and safety management



Declaration of Environmental Commitment

As a member of the Kirin Group, which aspires to be a low carbon corporate group, Kyowa Hakko Kirin declared its commitment to protecting the global environment under the "Declaration of Environmental Commitment" in June 2010 and is making steady progress to meet the declared targets.

Progress made in our implementation of the Declaration of Environmental Commitment

Declaration	2010 results*1
We aspire to become a low carbon corporate group.	Greenhouse gas emissions (CO ₂): 700,000 tons (6.3% reduction over the 2005 level) Installed photovoltaic power generation facilities in the new research building within the Tokyo Research Park. The current cumulative number of hybrid vehicles introduced: 339
We will promote resource conservation.	Promoted green procurement throughout the supply chain. Achieved zero waste emissions across the group for six years in a row.
We will actively work on environmental conservation and protection.	Conducted the Kirin Takasaki Water Source Forest Conservation Activities since 2007. Organized the Kirin Fuji-sanroku Water Source Forest Conservation Activities jointly with Kirin Distillery. Took part in various activities to protect water resources.
We will promote conservation of the environment and the ecological systems of local communities.	Conducted activities to protect water resources used by our plants. Conducted clean-up activities along the roads and rivers near each plant.

*1 Results between January and December 2010

Kyowa Hakko Kirin Declaration of Environmental Commitment

We declare our active commitment to protecting the global environment for generations to come.

- **We aspire to become a low carbon corporate group.**
 - We will reduce CO₂ emissions of the Kyowa Hakko Kirin Group by 15% over the 2005 level by 2020.
 - We will promote the use of renewable energy.
 - We will reduce energy consumption in the administrative division by 1% annually.
 - We will introduce 1,000 hybrid vehicles for field salespeople by 2014 to encourage eco-driving.
- **We will promote resource conservation.**
 - We will actively promote the procurement of raw materials, office supplies, equipment, and other items with a low environmental impact.
 - We will promote the separation of garbage and reduction of waste to maintain zero emissions.
- **We will actively work on environmental conservation and protection.**
 - We will minimize the impact of our business activities on the environment, safety, and health throughout the life cycle of products from R&D to production, marketing, use, and disposal.
 - We will deliver environmentally friendly products and services.
- **We will promote conservation of the environment and the ecological systems of local communities.**
 - We will promote environmental conservation activities such as forest conservation projects.
 - We will work toward environmental beautification through activities such as keeping local communities clean.

Yuzuru Matsuda

President & Chief Executive Officer
Kyowa Hakko Kirin Co., Ltd.

Environmental and safety audits

In fiscal 2010, environmental and safety audits were conducted at 36 business sites of 12 companies. No legal violations in connection with the environment and safety subject to punitive measures were identified, nor were environmental accidents. The major areas for improvement identified in the audits are as shown below.

Major areas for improvement identified in the environmental and safety audits

Safety audit	<ul style="list-style-type: none"> • Safety measures for locations where an oxygen shortage may occur (Takasaki Plant) • Improvement of the risk assessment system (Ube Plant, Kyowa Hakko Bio Yamaguchi Production Center [Hofu]) • Preparation of documents related to safety and health (Fuji Plant)
Environmental audit	<ul style="list-style-type: none"> • Promotion of environmental close call follow-up (Takasaki Plant) • Promotion of energy conservation for research facilities (Fuji Plant, Fuji Research Park, Tokyo Research Park) • Development of a system that allows production schedules to be shared with the environmental facility management division (Kyowa Medex Fuji Plant)

Environmental, safety, and product safety assessments

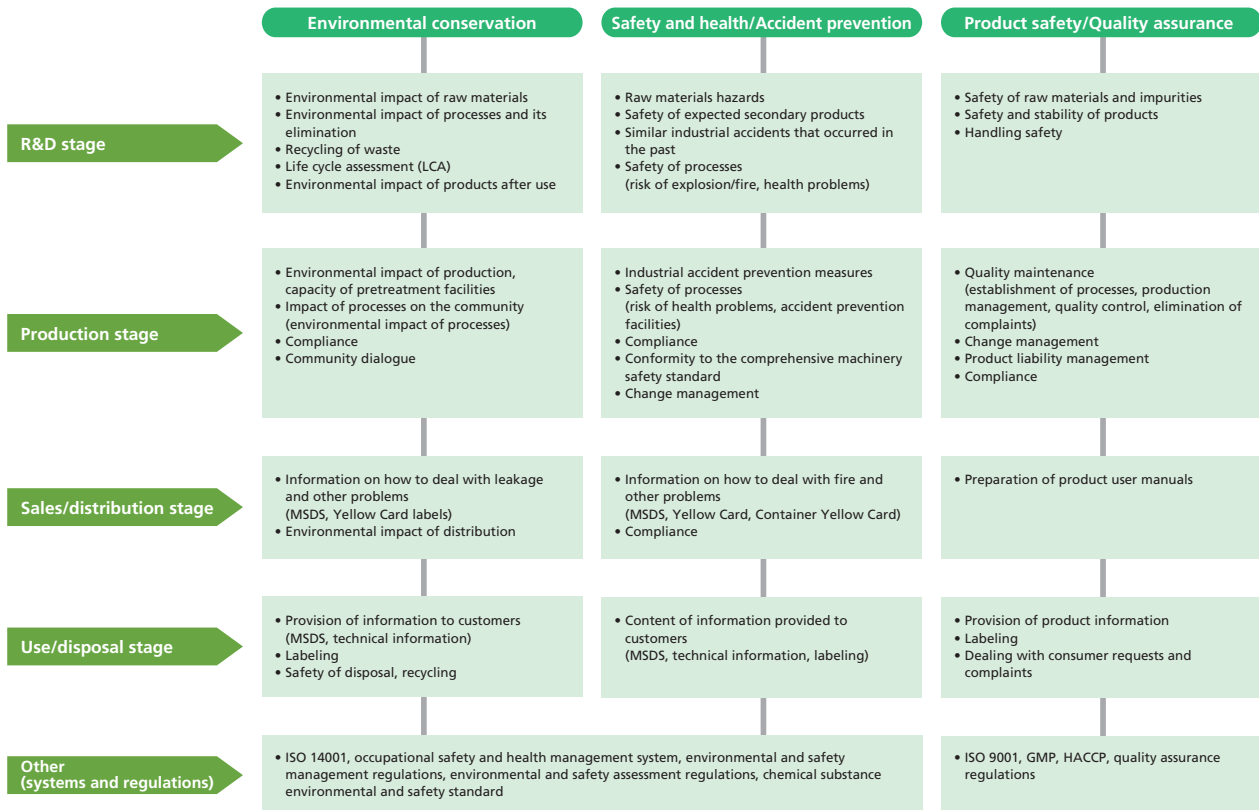
Based on its own Basic Policy on the Environment, Safety, and Product Safety, as well as under the Responsible Care*2 initiative for environmental protection and safety, the Kyowa Hakko Kirin Group operates rigorous assessments at each stage of the product life cycle, from R&D through to use and disposal.



Responsible Care

*2 **Responsible Care:** A voluntary initiative under which companies handling chemicals continuously improve their health, safety, and environmental performance at every stage of the product life cycle, from the development of chemical substances to production, distribution, use, final consumption, and disposal, publish the results of their activities, and promote dialogue and communication with other sectors of society.

Environmental, safety, and product safety assessments



Action Plans and Performance in Fiscal 2010

Action Guideline	Initiative	Fiscal 2010 Targets
Guideline for Action 1 Upgrade environmental and safety functions and maintain the environment and safety	Maintenance and expansion of ISO 14001 environmental management system	Maintain company-wide integrated ISO 14001 certification for Kyowa Hakko Kirin. Maintain ISO 14001 system at Kyowa Hakko Bio, Kyowa Hakko Chemical, and Daiichi Fine Chemical.
	Accidents	Zero industrial/environmental/safety-related accidents
	Environmental and safety audits	Conduct audits at all consolidated subsidiaries.
	Environmental and safety risk assessment	Ensure that environmental and safety risk assessments and comprehensive machinery safety standards are fully implemented.
Guideline for Action 2 Minimize environmental and safety risks	Ensuring compliance	Zero legal violations, zero complaints
	Development of waste governance system	Conduct audits at no less than 90% of partner waste contractors.
Guideline for Action 3 Enhance environmental performance	[Production and R&D]	
	Eco Project (realization of low carbon corporate group)	
	• Global warming prevention (CO ₂ emissions)	Reduce CO ₂ emissions by at least 3% from the fiscal 2007 level by fiscal 2012.
	• Per-unit energy consumption	Reduce per-unit energy consumption by at least 1% annually.
	• Final landfill disposal volume	Maintain zero waste emissions. The target is to reduce emissions to at least 105 tons by fiscal 2010.
	• Reduction of chemical substance emissions	Reduce chemical substance emissions by 50% from the fiscal 2003 level by fiscal 2010.
	Distribution environment and safety	Rationalize distribution, and ensure environmental conservation and safety in distribution. Introduce 1,000 hybrid vehicles for field salespeople by 2014.
	[Administration]	
	Green Office Plan (GOP)	Reduce power consumption by at least 1% annually. Reduce the use of photocopy paper by at least 5% over three years. Green purchasing rate: 80% (value basis)
	Challenge 25 Campaign	Take part in Challenge 25 Campaign.
	Guideline for Action 4 Consider the environment throughout the entire product life cycle	LCA/Material balance
Green procurement		Promote green procurement.
Guideline for Action 5 Provide safe and useful products	Consumer and product safety assurance	Promote the disclosure of comprehensive product information.

*1 Self-evaluation ◎: Target achieved ○: Target not achieved, but improved ✕: Target not achieved

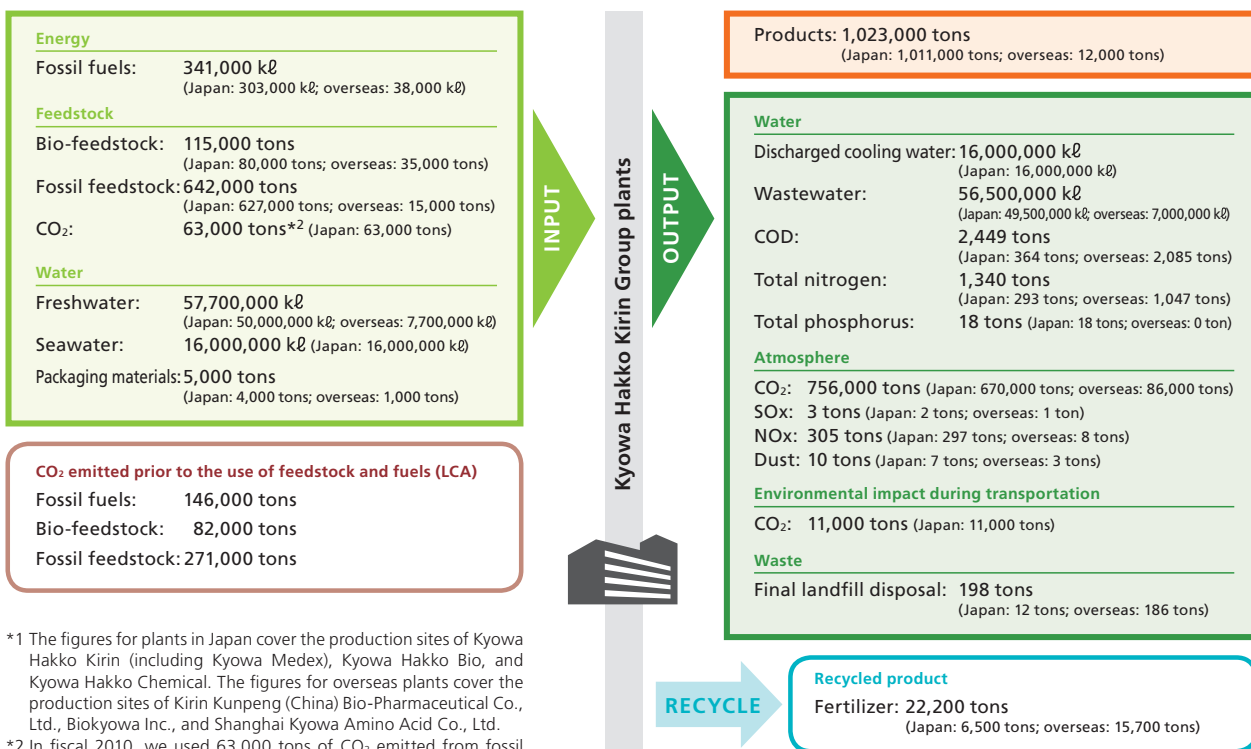
*2 Fiscal 2010 to fiscal 2012

*3 The figures are for the production and research sites of Kyowa Hakko Kirin, Kyowa Hakko Bio, Kyowa Hakko Chemical, and Kyowa Medex. The figures for CO₂ emissions, per-unit energy consumption, the number of industrial and other accidents and complaints also include the results for Daiichi Fine Chemical.

Fiscal 2010 Performance (Status of Progress)	Evaluation*1	Medium-term Targets*2	Page
Company-wide integrated ISO 14001 certification was maintained for seven business sites of Kyowa Hakko Kirin and Kyowa Medex. ISO 14001 certification was maintained at Kyowa Hakko Bio, Kyowa Hakko Chemical, and Daiichi Fine Chemical. (Preparations are currently underway to obtain company-wide integrated certification for Kyowa Hakko Bio by 2011.)	◎	Properly conduct internal audits and maintain integrated certification for Kyowa Hakko Kirin.	27
Lost time accidents: 2*3 Environmental accidents: 0 Safety-related accidents: 0	×	Zero industrial/environmental/safety-related accidents	23, 24
Audits were conducted at all business sites in Japan and overseas.	◎	Conduct audits at all consolidated subsidiaries.	28
Environmental and safety auditors confirmed that environmental and safety risk assessments were conducted properly at all business sites. It was confirmed at commercialization meetings that product safety data had been acquired.	◎	Reinforce environmental and safety risk assessments and comprehensive machinery safety standards.	28
No legal violations subject to punitive measures concerning the environment and safety Environmental complaints: 13*3 (noise etc. associated with the construction of a new building at the Tokyo Research Park: 9; odor: 1; fallen leaves: 2; other: 1)	○	Maintain zero legal violations subject to punitive measures concerning the environment and safety. Reduce environmental complaints.	28
Each business site conducted audits of their partner waste contractors. (72% covered)	○	Conduct audits at no less than 90% of partner waste contractors.	34
706,000 tons*3, 2.6% increase from the fiscal 2007 level	○	Reduce CO ₂ emissions by at least 3% from the fiscal 2007 level by fiscal 2012. Promote the use of renewable energy.	32
3.3% increase from the previous fiscal year at eight main plants	×	Reduce per-unit energy consumption by at least 1% annually at main plants.	32
Zero emissions were maintained (13 tons*3).	◎	Reduce final landfill disposal to 105 tons or less.	34
Chemical substance emissions: 435 tons, 39% reduction from the 2003 level	×	Reduce chemical substance (VOC) emissions by 50% from the fiscal 2003 level by fiscal 2012.	35
A periodical Specified Consigner report and plan were submitted according to the Act on the Rational Use of Energy. The per-unit energy consumption was improved in comparison with the previous fiscal year at Kyowa Hakko Bio. All existing field salespeople's vehicles are low-emission vehicles, of which 448 vehicles (cumulative) are hybrid vehicles.	◎ ○	Rationalize distribution, and ensure environmental conservation and safety in distribution. Introduce 1,000 hybrid vehicles for field salespeople by 2014.	— 32
0.9% decrease from the previous fiscal year's level	○	Reduce power consumption by at least 1% annually.	32
0.6% decrease from the previous fiscal year's level, but 17% increase from the fiscal 2008 level	×	Reduce the use of photocopy paper by at least 5% over three years.	32
Green purchasing rate of office supplies: 84%	◎	Maintain green purchasing rate at 80% or more.	32
The Declaration of Environmental Commitment was issued, and Cool Biz dress code campaign and various energy conservation activities were conducted at offices.	◎	Promote the implementation of the Declaration of Environmental Commitment.	27
Material balance and environmental impact were analyzed, and all businesses continued to be assessed based on life cycle assessment (LCA), resource efficiency, and emission intensity.	◎	Continue LCA and material balance assessments for all businesses.	31
The consumable supplies purchasing system was upgraded to enable the identification of environmentally friendly products.	◎	Promote procurement of raw materials, office supplies, equipment, and others with low environmental impact (green procurement).	33
The proper management of materials safety data sheets (MSDS) and the disclosure of product safety information were promoted.	◎	Promote the disclosure of comprehensive product information.	18

Working on the Reduction of Environmental Impact

Material Balance — the Kyowa Hakko Kirin Group (domestic and overseas plants)*1



*1 The figures for plants in Japan cover the production sites of Kyowa Hakko Kirin (including Kyowa Medex), Kyowa Hakko Bio, and Kyowa Hakko Chemical. The figures for overseas plants cover the production sites of Kirin Kumpeng (China) Bio-Pharmaceutical Co., Ltd., Biokyowa Inc., and Shanghai Kyowa Amino Acid Co., Ltd.

*2 In fiscal 2010, we used 63,000 tons of CO₂ emitted from fossil feedstock and 27,000 tons of CO₂ emitted from fuels as raw materials for the oxo process in the manufacturing of products, fixing 90,000 tons of CO₂ in total.

RECYCLE
Fertilizer: 22,200 tons
(Japan: 6,500 tons; overseas: 15,700 tons)

web Environmental and safety information for each plant belonging to the Kyowa Hakko Kirin Group
<http://www.kyowa-kirin.co.jp/english/csr/environmental/index.html>

Environmental Accounting

Environmental conservation cost			Major activities (FY2010)		Unit: Millions of yen	
					FY2009	
			Investment	Expense	Investment	Expense
(1) Business area cost			1,089	3,386	635	4,210
(1)-1 Pollution prevention cost	1) Cost of preventing water contamination	Investment and maintenance cost for water contamination control facilities	617	1,626	275	1,957
	2) Cost of preventing air pollution and other pollution	Investment and maintenance cost for air pollution control facilities, deodorization facilities, etc.	142	316	83	472
(1)-2 Global environment conservation cost			257	400	237	488
(1)-3 Resource circulation cost			73	1,044	40	1,293
(2) Upstream/downstream cost			0	57	0	58
(3) Administration cost			8	345	23	380
(4) R&D cost			0	758	4	1,476
(5) Social activity cost			0	17	0	15
(6) Environmental remediation cost			0	8	0	10
Total			1,097	4,571	662	6,149

Economic benefit		Unit: Millions of yen	
Activities (FY2010)		FY2009	FY2010
Total investment	Expansion and rationalization of production and research facilities	22,362	17,792
Total R&D cost	R&D for new products and technologies	34,676	44,162
Sales of valuables in connection with (1)-3 and (2)	Sale of dried fungus fertilizer, used catalysts, and by-product oil	77	73
Resource-saving effects in connection with (1)-2 and (1)-3	Energy and resource conservation and waste reduction	106	125

Notes: - The figures cover production sites and laboratories of Kyowa Hakko Kirin (including Kyowa Medex), Kyowa Hakko Bio, and Kyowa Hakko Chemical.
 - The environmental accounting for fiscal 2010 shows the data from between January 1 and December 31, 2010, which were calculated in accordance with the Environmental Accounting Guidelines 2005, published by the Ministry of the Environment. (The data for fiscal 2009 cover a period of only nine months from April 1 to December 31, 2009, due to the change to the fiscal year end.)
 - Green purchasing statistics represent the purchase amount of environmentally friendly products, including Eco Mark products, and have been included as reference information.

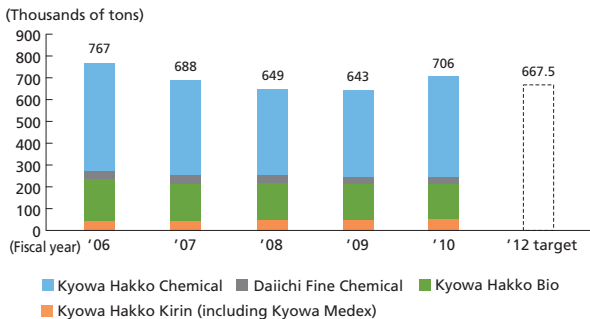
Efforts to Reduce CO₂ Emissions in All Business Activities

Our Activities for Reducing CO₂ Emissions

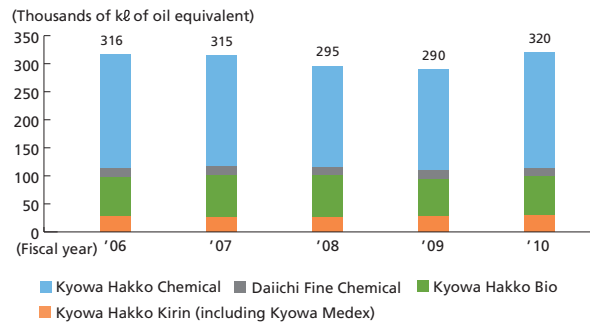
The Kyowa Hakko Kirin Group's goal is to reduce CO₂ emissions by 3% from the fiscal 2007 level by fiscal 2012, and by 15% from the fiscal 2005 level by fiscal 2020. The total CO₂ emissions in fiscal 2010 were 706,000 tons, up 2.6% compared with fiscal 2007, due to recovering production. The increased production also pushed up energy consumption in fiscal 2010 by 10% year on year to 320,000 kiloliters in oil equivalent. Per-unit energy consumption, however, increased by 3.3% compared with the previous fiscal year due to the change in our product mix brought about by the reorganization of the livestock and fishery and alcoholic beverages businesses.

In fiscal 2010, we introduced at our plants highly efficient freezers, low power consumption air conditioners, gas boilers (fuel switching), LED lighting, and other energy-saving measures, and optimized ethanol distillation and other processes. We also installed a photovoltaic power generation system at the Tokyo Research Park as part of our efforts to produce more renewable energy.

CO₂ emissions



Energy consumption



Eco Project

The Kyowa Hakko Kirin Group is working to prevent global warming and achieve zero waste emissions under the Eco Project launched in 1998. An annual Eco Project debriefing session was held in August 2011, where 30 representatives from 13 business sites of Kyowa Hakko Kirin and its group companies met to report their activities for fiscal 2010. Thanks to this Eco Project, we were able to reduce CO₂ emissions by 5,800 tons in fiscal 2010.



Eco Project debriefing session

Replacing existing sales vehicles with hybrid vehicles

At Kyowa Hakko Kirin, all company vehicles used by MRs have been replaced with low-emission vehicles to encourage eco-driving. We went a step further in 2009 by launching a project to replace about 1,000 field salespeople's vehicles with hybrid vehicles by 2014. When this project is completed, it is expected that CO₂ emissions will be reduced by 1,723 tons annually in comparison with the current fleet, which consists mainly of vehicles powered by a 1,500 cc gasoline engine. The number of hybrid vehicles introduced as of the end of March 2011 totaled 448. We also observe "No car days" twice each month, when field salespeople are not permitted to use their vehicle at all.

Green Office Plan (GOP)

As part of its ISO 14001 activities, the Kyowa Hakko Kirin Group has set the targets shown below for all administrative divisions at the Head Office, plants, research facilities, and sales offices, and conducts various activities to achieve them in cooperation with the labor union and general affairs divisions. Fiscal 2010 saw power consumption cut by 0.9% compared with the previous fiscal year and the green purchasing rate rise to 84%. However, despite reducing the use of photocopy paper by 0.6% on a year-on-year basis, we ended up with a 17% increase from the fiscal 2008 level. This means that we could not achieve our target of reducing the use of photocopy paper by at least 5% over three years. We will continue our efforts to achieve our original targets.

GOP targets

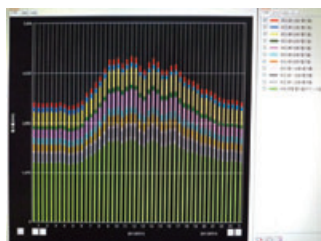
- Reduce power consumption by at least 1% annually.
- Maintain the green purchasing rate at 80% or more.
- Reduce the use of photocopy paper by at least 5% over three years.

Promoting green procurement

Under its Green Procurement Guidelines, the Kyowa Hakko Kirin Group is performing various environmental activities to institute low carbon group operations across the supply chain. Our purchasing system for consumable goods enables the identification of environmentally friendly products, helping us to increase our spending on green procurement items to more than 50 million yen in fiscal 2010. We are also actively promoting the use of eco-friendly ink, the introduction of machinery and equipment with low environmental impact, energy conservation through the utilization of renewable energy and resource conservation based on active recycling, and the adoption of the latest construction methods that are compatible with global environmental protection. Furthermore, we survey raw material suppliers so as to strengthen mutual cooperation in regard to environmental commitment.

Energy conservation at the Fuji Plant and the Fuji Research Park

In fiscal 2010, the Fuji Plant worked to conserve energy through the optimum operation of the large freezers introduced between 2006 and 2009, resulting in a reduction in energy consumption of 72 kiloliters in oil equivalent/year from the fiscal 2006 level. At



Visual display of energy consumption on a PC

the Fuji Research Park and the Drug Formulation Research and Development Laboratories, motion sensor lighting was installed to eliminate unnecessary use of energy, and thermal insulation window films were employed to help enhance energy-saving effects. The Fuji Plant and the Fuji Research Park also developed a system to visualize the electricity consumption trend of each plant building and display it on PCs in every workplace with a view to raising employee energy-saving awareness.

We will continue our efforts for energy conservation by realizing more detailed visualizations of energy consumption as well as by replacing absorption freezers used at the Fuji Research Park and the Drug Formulation Research and Development Laboratories with more energy-efficient models.

Energy conservation at the Tokyo Research Park

The new research building completed in the spring of 2010 at the Tokyo Research Park is designed to be energy conscious and equipped with high-frequency (HF) fluorescent lamps,*1 LED lighting, dimmer lighting systems for offices, ice thermal storage air conditioners, heat-reflecting glass, and a photovoltaic power generation system. In addition, power consumption at the park is shown on the website to enhance the energy-saving awareness of employees and encourage them to conserve energy in their daily research and business activities. We are currently developing a new system that will allow us to gather and display energy consumption data for individual pieces of equipment.



Photovoltaic power generation facilities on the rooftop of the new research building

*1 **High-frequency (HF) fluorescent lamps:** A type of lamp with high luminous efficiency operated by high-frequency electronic ballasts

Energy conservation at the Takasaki Plant

Many of the production facilities at the Takasaki Plant are more than 20 years old and not efficient in terms of energy conservation. These facilities are being renovated gradually according to a plan, and in fiscal 2010, the air-conditioning equipment and control system of the manufacturing building were upgraded. In conducting this work, priority was given not only to energy saving but also to cost saving, meaning that only essential elements were replaced rather than the entire system and idle equipment was effectively utilized. Through these efforts, it is expected that energy consumption will be reduced by 13.5 kiloliters in oil equivalent/year (22 ton CO₂/year in CO₂ emissions).



New air handling unit



New closed cooling tower

Reinforcing the Waste Governance System to Ensure Proper Disposal

Our Activities for Reducing Waste

Waste governance

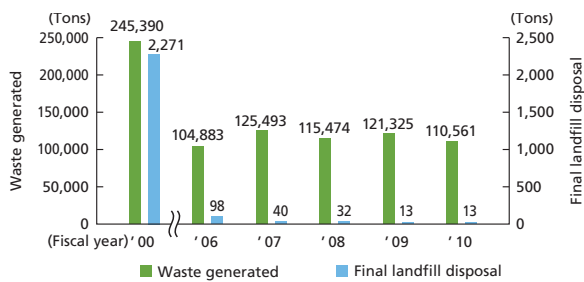
The Kyowa Hakko Kirin Group ensures that its waste contractors dispose of waste properly by conducting inspections prior to and regularly after contracting out waste disposal in order to help prevent illegal dumping. We are continuously reinforcing our governance system to make it even more effective and reliable through such measures as allowing auditors at one business site to audit another business site and reviewing disposal outsourcing contracts.

Zero emissions activities

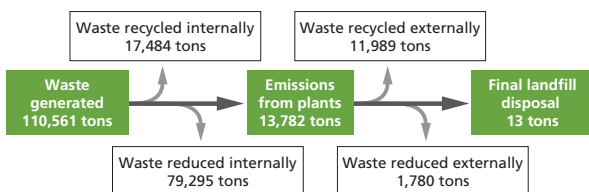
The total amount of waste generated by the group during fiscal 2010 was 110,561 tons. Of this, the final landfill disposal volume was 13 tons, meeting our goal of 105 tons or below. The percentage of the final landfill disposal of total waste generated is as low as 0.01% thanks to the waste recycling and reduction efforts made within the plants and by outside waste contractors. We thus achieved zero emissions*2 for the sixth consecutive year.

*2 While "zero emissions" generally means reducing waste to zero, the Kyowa Hakko Kirin Group uses this term to mean maintaining final landfill disposal as a percentage of total waste at 0.1% or less.

Waste generated and final landfill disposal



Recycling/disposal flow of waste (fiscal 2010)



Promotion of reuse and recycling

At the Kyowa Hakko Bio Yamaguchi Production Center (Hofu), phosphorus contained in fermentation wastewater is made insoluble through lime precipitation and dehydrated on a filter to produce a cake of calcium phosphate as a pretreatment for the biological treatment of the wastewater. The cake is then removed from the wastewater treatment process. We were previously removing phosphorus by feeding a large amount of lime into the biological treatment. However, this method generated calcium carbonate and other inorganic components and increased waste sludge. The new method has led to decreased waste sludge and reduced phosphorus in the plant's wastewater.

The phosphorus content in the dehydrated cake is about 29% in P₂O₅ equivalent, which is almost the same as that in phosphate ore. We are therefore drying some of the cake produced and providing it as a material for fertilizers and other products. We will promote the reuse of the dehydrated cake as a valuable resource by introducing a dryer and other necessary equipment.



Filter



Dehydrated cake

Appropriate disposal of PCBs

Used capacitors, transformers, circuit breakers, and lighting ballasts are stored in locked warehouses provided with measures to prevent chemical seepage in accordance with the special industrial waste storage standards. Each business site has already applied to the Japan Environmental Safety Corporation (JESCO) for the treatment of PCB waste.

Polychlorinated biphenyl (PCB) waste stored

Capacitors, transformers, circuit breakers	154
Lighting ballasts	4,184
Low-level PCB oil	1,318 liters

(As of March 31, 2011)

Reducing Chemical Releases to Lessen the Impact on the Global Environment

Activities for Reducing Chemical Releases

Curbing emissions of 12 important chemical substances

We saw a decrease from 11.2 tons in fiscal 2009 to 8.3 tons in fiscal 2010 in emissions of the 12 chemical substances designated by the chemical industry as priority substances requiring particular attention. The decrease occurred because the amount of ethylene oxide handled, which increased in fiscal 2009, decreased in fiscal 2010.

Soil pollution risk management

The Kyowa Hakko Kirin Group makes it a rule to conduct soil contamination inspections when buying or selling land and when discontinuing the use of regulated substances based on the soil pollution countermeasure regulations established in 2004. There were no circumstances that required soil inspections in fiscal 2010.

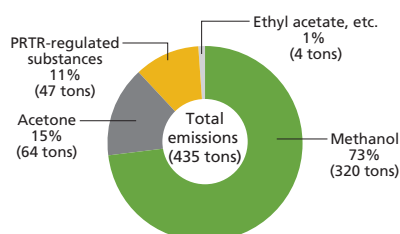
Preventing ozone layer depletion

The Kyowa Hakko Kirin Group has been gradually replacing its large freezers in line with a specific plan. The emissions of specified chlorofluorocarbons in fiscal 2010 were 0.7 tons.

Reducing VOC emissions

In fiscal 2010, the emissions of volatile organic compounds (VOCs) increased by 17%, from 374 tons in fiscal 2009 to 435 tons in fiscal 2010, due to recovering production. This increase was driven by emissions of methanol, which rose by 62%, from 197 tons in fiscal 2009 to 320 tons in fiscal 2010 due to a recovery in production. Emissions of VOCs other than methanol, however, decreased by 35%, from 176 tons in fiscal 2009 to 115 tons in fiscal 2010. We are currently working to improve the process and facilities needed to facilitate the recovery of methanol and other VOCs.

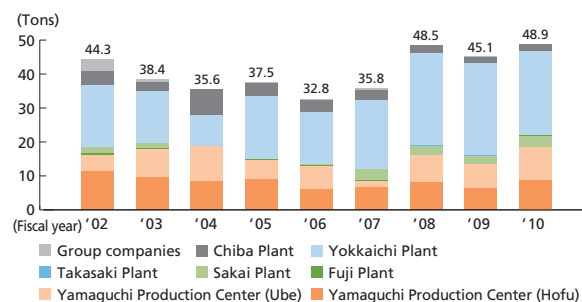
VOC emissions in fiscal 2010



Curbing emissions of PRTR Class 1 chemical substances

The group's emissions of chemical substances designated under the so-called Pollutant Release and Transfer Register (PRTR) law (Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof) as Class 1 chemical substances increased by 8.4% year on year to 48.9 tons. This was due to both brisk production and a fiscal 2010 revision to the PRTR law that saw the number of Class 1 specified chemical substances increase from 354 to 462.

Emissions of PRTR Class 1 chemical substances



Emissions of PRTR Class 1 chemical substances in fiscal 2010

Cabinet-Order-designated No.	Substance name	Releases into the air (tons)	Releases into water (tons)	Releases into the soil (tons)
12	Acetaldehyde*1	1.10	0.97	0.00
13	Acetonitrile	0.02	0.00	0.00
20	2-aminoethanol	15.04	1.00	0.00
35	Isobutylaldehyde*2	0.52	1.50	0.00
53	Ethylbenzene	5.32	0.00	0.00
56	Ethylene oxide*1	1.00	0.86	0.00
80	Xylene	12.70	0.00	0.00
104	Chlorodifluoromethane (HCFC-22)*3	0.35	0.00	0.00
127	Chloroform*1	4.02	0.00	0.00
132	Cobalt and its compounds	0.01	1.40	0.00
232	N,N-dimethylformamide	0.84	0.00	0.00
257	Decyl alcohol*2	0.01	0.00	0.00
275	Sodium dodecyl sulfate*2	0.00	0.02	0.00
288	Trichlorofluoromethane (CFC-11)*3	0.35	0.00	0.00
295	3,5,5-trimethyl-1-hexanol	0.24	0.00	0.00
300	Toluene	0.95	0.00	0.00
319	1-Nonanol*2	0.01	0.00	0.00
392	Normal-hexane*2	0.03	0.00	0.00
398	Benzyl chloride	0.06	0.01	0.00
400	Benzene*1	0.34	0.00	0.00
411	Formaldehyde*1	0.03	0.00	0.00
413	Phthalic anhydride	0.19	0.00	0.00
Total		43.13	5.76	0.00
179	Dioxins (mg-TEQ)	53.8	1.0	0.0

*1 Substances that are also included in the 12 chemical substances designated by the chemical industry

*2 Substances that were added to the list of Class 1 chemical substances in the revision to the PRTR law in fiscal 2010

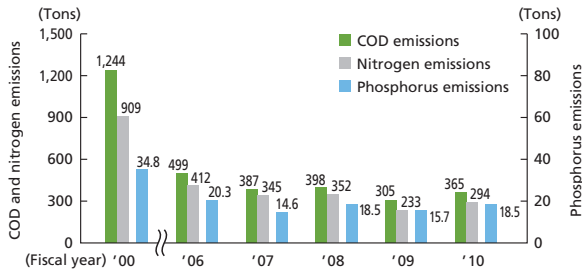
*3 Substances that were used as CFC refill for freezers

Promoting the Refurbishment of Facilities for Purifying Wastewater and Atmospheric Emissions

Activities for Preventing Water Contamination

The Kyowa Hakko Kirin Group is actively working on the improvement of production processes and investing in the refurbishment of wastewater treatment facilities so as to reduce chemical oxygen demand (COD), nitrogen, and phosphorus—the three major wastewater pollution indicators.

Chemical oxygen demand (COD), nitrogen, and phosphorus emissions from the Kyowa Hakko Kirin Group



Wastewater management at Kyowa Hakko Kirin Takasaki Plant

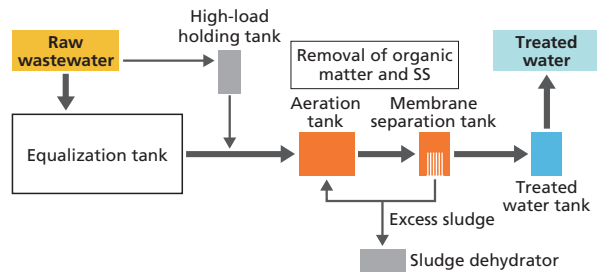
Since the Takasaki Plant and the Bio Process Research and Development Laboratories respectively constitute the company's major production center and major research center, the wastewater from these sites contains high organic matter and requires stringent water management. We therefore upgraded our wastewater treatment plant in 2009 when our new therapeutic antibody substance production facility was constructed to ensure stable treated water quality and reduced environmental impact. The new plant's larger capacity equalization tank equalizes the content of organic matter and wastewater volume, which fluctuate greatly depending on the production process, while a membrane filtration*4 system effectively ensures that organic matter and suspended solids (SS) contained in wastewater from the sites are safely below the legal limits. The adoption of the membrane treatment has improved the treatment quality significantly, and stable wastewater management is maintained at the sites through frequent membrane cleaning, daily wastewater loading simulation, information sharing among departments, environmental assessment of new products, and other collaborative efforts across the sites.



Wastewater treatment plant

*4 **Membrane filtration:** A wastewater treatment process in which solids are separated from liquid using a membrane filter after organic matter is biologically removed

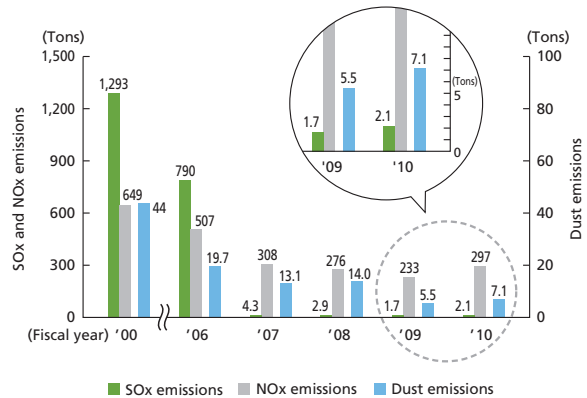
Wastewater treatment flow



Activities for Preventing Air Pollution

The Kyowa Hakko Kirin Group is actively advancing the switch to alternative boiler fuels and the upgrading of facilities in order to reduce emissions of sulfur oxide (SOx), nitrogen oxide (NOx), and dust—the three major air pollution indicators.

SOx, NOx and dust emissions at the Kyowa Hakko Kirin Group



Emissions reduction at Kyowa Medex Fuji Plant

In December 2010, Kyowa Medex implemented a project to upgrade its obsolete boiler, including switching fuel from heavy oil to liquefied petroleum gas (LPG). Through this fuel switch and other efforts, we aim to reduce CO₂ emissions by 13%, or 130 tons, from the fiscal 2009 level. The elimination of the use of heavy oil is also expected to reduce emissions of SOx, NOx, dust, and other air pollutants. Annual emissions of SOx and NOx are projected to be reduced by 0.38 tons, or 100%, and by 0.5 tons, or 50%, respectively, from fiscal 2009 levels.

Protecting Water Resources to Maintain Ecosystems

Water-source Protection Project

To maintain ecosystems and biodiversity, it is necessary to protect the water resources that sustain natural living networks. Water is also an indispensable resource for the fermentation production process. The Takasaki Plant of Kyowa Hakko Kirin (former Kirin Pharma) started to take part in the Kirin Group's water-source protection project in fiscal 2007, and Kyowa Hakko Kirin Fuji Plant, Kyowa Hakko Bio Yamaguchi Production Center, Kyowa Hakko Kirin Ube Plant also joined the project in fiscal 2009.

Activities at Kyowa Hakko Kirin Takasaki Plant

At the 4th Kirin Takasaki Water Source Forest Conservation Activities held on October 16, 2010, participants worked with NPOs such as Forest Gunma 21 (FG21) to keep the forest in one of the water source areas of Takasaki City clean. The children who participated enjoyed making wood crafts and drawings. The project helped the 120 participants including employees from the Kirin Group deeply understand the importance of forest conservation and develop good mutual relationship by working together.



Children making wood crafts and drawings

voice

Hand the Green Baton to the Next Generation through the Kirin Takasaki Water Source Forest Conservation Activities

Mr. Teruhide Kikugawa

The NPO Forest Gunma 21 (FG21)



I've been assisting with the Kirin Takasaki Water Source Forest Conservation Activities for forest conservation as a volunteer, participating in the project every year since 2007 when it began. The forest seems to have become more and more beautiful year by year, providing a constant supply of clean water for us. I would like to continue working for the forest with participants from Kyowa Hakko Kirin for years to come.

Activities at Kyowa Hakko Kirin Fuji Plant

The Kirin Fuji-sanroku Water Source Forest Conservation Activities, a joint project with Kirin Distillery, was implemented twice in fiscal 2010, on May 22 and September 18. A total of 92 employees and their family members in the Mishima area took part in this project.



Improvement cutting

The participants divided into two groups, one of which took part in improvement cutting (removal of undesirable trees), while the other enjoyed a guided walk through the forest and a craft-making session.

Activities at Kyowa Hakko Bio Yamaguchi Production Center

Kyowa Hakko Bio Yamaguchi Production Center, along with Kyowa Hakko Kirin Ube Plant, joined the water-source protection project in fiscal 2009. The second round of activities was implemented around Lake Ohara on the upper Saba river, the water source for the Yamaguchi Production Center (Hofu), on November 13, 2010, under the slogan "Create living networks!" About 80 employees and their family members cut the undergrowth and performed other work under the guidance of staff from the Yamaguchi Prefecture Agriculture and Forestry Office. By joining the activity, participants deepened their understanding of the important role of forests.



Participants in the project

Environmental Conservation Activities for Local Communities around Our Business Sites

Each of our business sites conducts activities to show its commitment to protecting its local ecosystems. Such activities include cleaning up the Gamo-higata tidal flat, a wild bird migration site in Miyagi Prefecture, releasing young *amago* (red-spotted *masu* trout) into the Momozawa river in Shizuoka Prefecture, and protecting the grasslands in Akiyoshidai in Yamaguchi Prefecture. Each activity is conducted in cooperation with local communities. We also regularly take part in various events to clean up the areas around our business sites, including the "Kannyonama Clean-up Volunteer Day" in Gunma Prefecture, "30 Million Persons Seto Inland Sea Clean-up Campaign," and "Clean-up Campaign Sakai."

Reflecting Stakeholders' Opinions in Our Future Corporate Activities

CSR

Mr. Hideto Kawakita

CEO, International Institute for Human, Organization and the Earth (IIHOE)



This review was written based on the contents of this CSR Report and interviews with employees responsible for environmental management, safety, procurement, human resources, and CSR. I confirm that Kyowa Hakko Kirin has effectively begun the PDCA management cycle on fundamental issues in CSR.

Highly evaluated achievements

- To create a work environment in which a diverse group of employees can fully demonstrate their abilities, Kyowa Hakko Kirin has established the cross-company Diversity & Inclusion Project (D&I PJ), and in fiscal 2011 has been promoting activities aimed at “creating a corporate culture in which gender presents no barrier to any employee seeking to further their career” (page 20). I strongly hope that the company will continue its efforts to achieve the goal of creating “a motivational culture that bolsters all employees regardless of gender, nationality, the route by which they joined the company, life stage, or disability” by fiscal 2015.
- In addition to its continued efforts to annually recycle more than 20,000 tons of phosphorus contained in wastewater as materials for fertilizers, the company has also started to insolubilize and dehydrate phosphorus to produce calcium phosphate cake as a pretreatment for biological treatment of the wastewater (page 34). I hope that the company will promote the proper and effective utilization of the dehydrated cake as fertilizer, and make sure that consideration is paid to wastewater treatment even at the R&D stage of product development.

Efforts that have shown progress but require more commitment

- Kyowa Hakko Kirin took proper measures after discovering the inappropriate management of transgenic mice at its Tokyo Research Park (page 24). While this is commendable, I also hope that, as I pointed out last year, scenarios involving more than one accident occurring simultaneously will be incorporated into the business continuity plan (BCP) and that training based on those scenarios will be conducted. I would also like to see initial incident responses and disclosure of information implemented in a timelier manner.

- The percentage of Kyowa Hakko Kirin employees who took leave or availed themselves of the shorter working hours system to participate in childcare, long-term care, or nursing duties reached 4.65% (page 21). While this is praiseworthy, I also have high hopes that the company will actively publicize these cases among their colleagues as, from the age composition of the company’s workforce, I expect the number of employees who would need to participate in such systems will increase in the future.
- Kyowa Hakko Kirin has established the clear medium- to long-term goals of reducing greenhouse gas emissions by 3% from the 2007 level by 2012, and 15% from the 2005 level by 2020 (page 32). While this is admirable, I am concerned at the increase in CO₂ emissions, energy consumption, and per-unit energy consumption resulting from increased production and the business reorganization. I strongly hope that further reduction efforts—which do not simply rely on the introduction and replacement of equipment but on continuous and proactive innovation and improvement by employees at each business site—will be made across the company.

Points where further efforts are expected

- Procurement of raw materials: I am deeply concerned that the company, as noted last year, is still yet to establish a plan to prompt raw material suppliers to fulfill their CSR. I would recommend that upon gaining an understanding of how its suppliers are implementing their CSR, the company focus not only on safety, efficacy, and costs but also pay greater attention to reducing environmental impacts during collection, production, and refining processes, as well as promoting the human rights of the people engaged in the processes and those living near the sites. In addition, to preserve biodiversity at raw material/sample collection sites, it is important to give appropriate consideration to and take the necessary action for access and benefit-sharing (ABS) for local residents.
- Employment of people with disabilities (page 21): As I did last year, I would recommend that group-wide efforts be made to expedite the creation of jobs for people with disabilities through a wide and detailed study of the best practices of other companies. This will help the group achieve the statutory employment ratio for employees with disabilities as soon as possible. At the same time, encouraging the formation of a community in which employees with disabilities can advise and support each other would also be effective in helping them remain in their jobs for as long as possible.

profile

IIHOE: A nonprofit organization founded in 1994 for the purpose of promoting “democratic and balanced development of all the lives on the Earth.” While its main mission is to provide management support to other NPOs and social entrepreneurs, IIHOE also offers CSR support to many major companies.
<http://blog.canpan.info/iihoe/> (Japanese only)



Employees

Develop greater corporate creativity

—I expect all employees to become involved in the diversity project—

Ms. Sachiko Fujii

President, NPO Global Enhancement of Women's Executive Leadership (GEWEL)

Even to someone like myself, who worked in the pharmaceutical industry for a long time, Kyowa Hakko Kirin's HR Philosophy is impressive. It sets out the basic principles on human resources management established to achieve the company's corporate goal of becoming a leading global specialty pharmaceutical company and to promote and embody the ideas contained in "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin." The company's strategy of specializing in the development of molecular targeted drugs and other biotechnological pharmaceuticals as well as drugs for rare diseases is widely admired and differentiates the company from its rivals in the Japanese pharmaceutical industry, which these days appears overrun with foreign companies. I expect the company will also exhibit considerable creativity in the area of marketing and engage in keen competition with other global pharmaceutical companies through proper branding to ensure its unique Japanese products are recognized globally.

The diversity project launched in October 2010 is a departure from the company's former monoculture and aims to transform it into a truly global organization with a competitive workforce. The implementation of diversity & inclusion (D&I) will allow the company to get the best out of its employees, mold them into true professionals, increase their respect for diversity, and enhance their pride and motivation to fully express their creative powers. At the same time, it will contribute to the fulfillment of the corporate philosophy and goals and the realization of an atmosphere that highly values the achievements of each employee. The diversity project will bring about all these benefits and I hope that all employees will follow its progress closely.

In order for Kyowa Hakko Kirin's credo, "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin," to fully penetrate the corporate culture at all levels so that employees will take pride in their work, discover their *raison d'être*, and implement its pledges, the company probably needs to promote the message continuously for five to 10 years.

When thinking about D&I, we must not forget about the patients and others stakeholders of pharmaceutical companies, who also form a diverse group. The composition of employees should match this diversity. For instance, with the percentage of female doctors increasing, is the approach taken by medical representatives (MR) equally meaningful for both male and female doctors? Is the efficacy of any given drug the same for both men and women or might it be different? I have no doubt that pharmaceutical companies whose concept of D&I is far reaching enough to encompass these differences will win a great deal of respect.

To create such a respected company, it is important for each employee to consider how they can incorporate the idea of D&I into their daily operations, implement related measures, and take part in the process of changing the corporate culture in cooperation with the diversity project team members. It is also important for top management to send clear messages to employees and take action on an ongoing basis to show their strong commitment to D&I. I expect the company to establish and implement an action plan for the diversity project and annual key performance indicators (KPIs) in line with the corporate strategy.

In order to realize D&I as part of the corporate strategy, companies need leaders who respect others, are aware of the importance of fostering different values, and act based on a global perspective.

profile

Graduated from Tokyo University of Science. Worked as a product manager at Sandoz and Novartis Pharma, and successfully engaged in the commercialization of Ternelin and Diovan from the premarketing stage. Diovan in particular became a blockbuster with annual sales exceeding 100 billion yen and its marketing attracted tremendous industry attention. Established the Diversity Promotion Office at Novartis Pharma in 2006. Left the company in 2008. Currently President of NPO Global Enhancement of Women's Executive Leadership (GEWEL) as well as a presenter of seminars on the marketing of pharmaceuticals.

Response to Third-party Reviews

The Kyowa Hakko Kirin Group's corporate social responsibility (CSR) is carried out largely in order to implement the Group Management Philosophy. We will continue to act responsibly by prioritizing quality, the environment, and compliance. Based on the recognition that CSR activities are an integral part of our business activities as well as a central management issue, we will reinforce our commitment to social contribution.

To fulfill our CSR, we must listen to and correctly understand the expectations and needs of society and must keep raising the bar to avoid becoming complacent.

I would like to express my sincerest gratitude to Mr. Hideto Kawakita, Ms. Sachiko Fujii, and Mr. Mitsuru Miyata for providing us with valuable insights into our CSR activities from an expert point of view. With regard to those of our achievements that received high marks, we will try hard to further expand them and avoid falling into complacency. As for the shortcomings pointed out, we will take these criticisms seriously and discuss how we can improve our activities for the next fiscal year and thereafter. The results will be reported in future CSR reports.

Mr. Kawakita rated highly our efforts over the



Society

Become a company that promotes human well-being through bio-pharmaceuticals

Mr. Mitsuru Miyata

Executive Leader Writer, Medical Dept. Nikkei Business Publications, Inc.

Low-molecular-weight chemically-synthesized drugs are quickly yielding their leading-edge position to bio-pharmaceuticals. Most Japanese pharmaceutical companies overlooked this trend, however, and during 1990s became preoccupied with the development of drugs for lifestyle-related diseases. As a result, they are now struggling as the patents for their mainstay products expire. In contrast to this, Kyowa Hakko Kirin is the one Japanese company that has been focusing on bio-pharmaceuticals and leading the international race in R&D. The POTELLIGENT® technology, developed based on sugar chain research, one of the areas in which Japan excels, has become a fundamental therapeutic antibody technology licensed by many pharmaceutical companies and bio-venture firms around the world. There is even a possibility that all therapeutic antibodies sold in the world may come to benefit from the technology within the next 10 years. Similarly to Intel, which dominates the CPU market, Kyowa Hakko Kirin is on its way to becoming a company that cannot be ignored in the world of therapeutic antibodies.

Above all, as President Matsuda said in his interview included in the CSR Report, I expect Kyowa Hakko Kirin to continue to deliver innovative drugs to patients as soon as possible. In my view, the company will best fulfill its basic social contribution by continuing to cultivate biotechnologies, considered to be an important source of new drugs, for at least next 50 years or so to find solutions for diseases for which no effective treatment yet exists, such as cancer, autoimmune disease, and Alzheimer's disease. To meet this expectation, I hope to see the company maintaining its keen insight into cutting-edge scientific and social developments and continuing to pursue bold challenges without being swayed by short-term trends. In other words, I hope the company will continue to pioneer its own path while maintaining its determination to promote human health and well-being. Kyowa Hakko Kirin was created from the merger of Kyowa Hakko, which was the first company in the world to commercialize amino acid fermentation, and Kirin

Pharma, which developed the world's first fully human antibody. Both companies gave birth to global standard biotechnologies, while maintaining Japanese traditions in research and science.

My second expectation is that Kyowa Hakko Kirin will become a Japanese company that is capable of delivering global innovations. Since 2000, Japan has produced the second-highest number of Nobel laureates, beaten only by the United States. Although China has recently overtaken Japan in terms of science and technology spending, Japan still holds third place. It is my hope that Kyowa Hakko Kirin will play a leading role in transforming lines of scientific and technological research pursued in Japan into innovations that will contribute to global prosperity.

My third expectation is that the company, which is extending its global reach by welcoming foreign companies such as the U.K.-based ProStrakan Group into its group, will continue to be committed to enhancing its openness to different cultures and will embrace diversity as a global citizen. Companies that rely solely on the Japanese market, which is shrinking due to lingering deflation, the declining birth rate and rapidly ageing population, will not achieve growth. Kyowa Hakko Kirin needs to expedite the globalization of its workforce, including its senior management.

Lastly, I would like to see Kyowa Hakko Kirin expand its "missionary" activities aimed at deepening understanding of the essence of biotechnology. Kyowa Hakko Kirin would do well to keep in mind that the understanding and support of ordinary citizens of the current and coming generations are indispensable if the company is to have a bright future in biotechnology.

profile

After joining Nikkei Inc. as editor of *Nikkei Medical*, a magazine published by Nikkei Business Publications, Inc., helped launch the Nikkei Biotechnology & Business magazine and later assumed the position of chief editor. Established Japan's first biotechnology portal site, "Biotechnology Japan." Currently serving as executive leader writer of medical department of Nikkei Business Publications and webmaster of Biotechnology Japan, among others.

past year to promote diversity. On the other hand, we also received harsh criticism from him on our raw materials procurement and employment of people with disabilities. We take these comments seriously and will make utmost efforts to develop necessary systems while working on the improvement of other issues pointed out in his review.

Ms. Fujii praised the uniqueness of our HR Philosophy. We will continue to base our activities on "Sharing Values, Aims, and Ideals; Team Kyowa Hakko Kirin." We also received valuable feedback on D&I. We cannot become a global, growing company

if we do not respect diversity. We will continue our efforts to transform our corporate culture.

Mr. Miyata also provided us with valuable comments on globalization and diversity. He also evaluated our biotechnology very highly. For the future, we will work hard to meet people's expectations regarding the role that we, as a Japanese company, should be playing in global technological development.

We will reflect this valuable feedback in our future activities in order to maintain the Kyowa Hakko Kirin Group's status as an organization that is trusted and supported by society.



Ken Yamazumi
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