

# Business Activities

ASKA Pharmaceutical, the Company's core subsidiary, was a pioneer in hormone preparations and now operates a pharmaceutical business. We do so with a sense of mission to deliver valuable pharmaceuticals and services as long as there are medical needs to be met, this being ASKA's DNA since its

founding. This DNA, handed down through generations of the Company, informs our value chain (research, development, production, reliability assurance, sales and provision of information, etc.) and is the driving force behind our success in taking on the challenge of realizing total healthcare.

## Innovative Drug Discovery Division

The Innovative Drug Discovery Division promotes the strengthening of research infrastructure, technology, and human resources to grow into an organization that can continuously create new drugs, and promotes open innovation by utilizing the research environment of the Shonan Health Innovation Park.

In terms of drug discovery activities, we are vigorously aiming for drug discovery in our three priority areas, while also leveraging our strengths to create new drugs targeting diseases in areas in which we identify unmet medical needs. As one initiative aimed at strengthening our research infrastructure, we have introduced ion channel drug discovery technology with a view to uncovering new areas of research. By speeding up the evaluation system and introducing an AI platform, we are striving for new target identification and value creation of known targets.

We think it is also important to license in the external assets by using open innovation. In addition to shortening the distance between ourselves and other companies by setting up a base in the Shonan Health Innovation Park, we are also participating in matching events such as BioJapan, BIO International Convention, etc. in order to access the drug discovery seeds and technologies held by universities and venture companies. From this fiscal year, we have opened our doors further to technology from academia by partnering with several Japanese pharmaceutical companies in soliciting research proposals from domestic academic institutions.

Through these initiatives we seek not only to enhance our research capabilities, but also to enrich our research pipeline and transform the organization into a fighting team.



**Yasuhiro Tsukimi**  
Assistant Division Director  
Innovative Drug Discovery  
Division  
ASKA Pharmaceutical Co., Ltd.

## Business Development Division

The Business Development Division comprises the Business Development Department, the Medical Affairs Department, and the Portfolio Management Department, and is chiefly responsible for product licensing, evidence-building, portfolio creation, and start-up investments.

ASKA Pharmaceutical has grown consistently over the years, driven primarily by newly released products including RIFXIMA, RELUMINA, and DroEthi. In the Ob/Gyn field, the company now holds the number one sales position in Japan.

The Business Development Division believes that ASKA Pharmaceutical as capable of continuing to grow over the medium term (next 10–20 years) as well, and aims to develop the company into one that not only offers therapeutic options to women, but indeed contributes to all aspects of women's healthcare, including prevention, testing and diagnostics, and prognosis.

Looking beyond the next decade, the Business Development Division will engage in licensing activities aimed at fleshing out the pipeline and evidence-building geared toward maximizing the value of existing products and drug candidates already in the pipeline.

Looking further ahead to 20 years out, the company seeks to contribute to total healthcare for women, going beyond pharmaceuticals to also include awareness-raising, health consultation services, testing, and follow-up care. To that end, we will use the ASKA Innovation Fund, a corporate venture capital (CVC) fund established in 2023, to offer start-ups support through investment and by offering other funds.



**Hitoshi Akikubo**  
Director  
Portfolio Management  
Department  
Business Development Division  
ASKA Pharmaceutical Co., Ltd.

## Development Division

The Development Division comprises the Development Planning Department, which formulates clinical development strategies, and the Clinical Development Department, which conducts clinical trials in line with those strategies. On a daily basis, we are engaged in activities to contribute to medical care based on the provision of safe and useful therapeutic drugs and devices to society as quickly as possible.

With the newly formulated vision of continuously developing new drugs, the Development Division holds team-building workshops to ensure that each and every member understands this vision and works toward a common goal. In order to build the development system into one capable of consistently developing new drugs while adapting to the rapidly changing medical environment, this division is endeavoring to optimize operations by clarifying the separation of roles between the two departments. We think this arrangement will hasten the discovery of new ideas and approaches and further expedite the development of high-quality new drugs. Amid advances in digital technology, this division has also initiated development of new digital therapeutics with a view to offering novel medical solutions. Members of the Development Division are working as one to develop pharmaceuticals and medical devices that address various medical needs, albeit with a focus on obstetrics and gynecology (Ob/Gyn) given ASKA Pharmaceutical's specialty pharma status in this field. The aim in doing so is to offer female patients as many treatment options as possible and as quickly as possible.



**Sachiko Nakagawa**  
Director  
Clinical Development  
Department  
Development Division  
ASKA Pharmaceutical Co., Ltd.

## Production Division

ASKA Pharmaceutical's Production Division ensures the stable supply of pharmaceuticals while also reducing costs through efficient production planning and quality control. The company operates a sustainable production system supported by state-of-the-art technologies.

ASKA Pharmaceutical has established rigorous production control in order to ensure a stable supply of top-quality pharmaceuticals. The company endeavors to provide reliable products, always placing top priority to patients' health and safety.

The company imposes strict quality control over every process, in compliance with Good Manufacturing Practice (GMP). In addition, the introduction of a Manufacturing Execution System (MES), Laboratory Information Management System (LIMS) and Quality Assurance System (QAS) has ensured production history traceability. This not only enables the company to act swiftly in the event that defects are discovered, but also contributes to stable supply and cost efficiency by allowing the company to plan production efficiently to match market demand. As the Production Division also puts considerable effort into human resources, the staff in charge of quality control and production control have high levels of specialist expertise and proficiency. Staff undergo regular training to maintain their skills and adopt the latest technologies and knowledge. The Production Division also pays due attention to the environment, pursuing sustainable production through the use of energy-saving equipment and waste recycling.

These initiatives enable ASKA Pharmaceutical to supply high-quality products in a timely and reliable fashion, contributing to patients' health and safety. Going forward, the company will continue to strengthen its production system with an eye toward ensuring sustainable growth.



**Hiroaki Yoshioka**  
Director  
Production Control Department  
Production Division  
ASKA Pharmaceutical Co., Ltd.

## Supply Chain Management

Our business is supported by numerous important business partners. The Group aims to develop together with its partners by building even more trusting relationships in order to maintain and improve the quality of its products and services and ensure stable supply.

The Group signed the United Nations Global Compact in FY2021 and supports the 10 principles related to the protection

of human rights, the elimination of unfair labor practices, environmental measures, and the prevention of corruption. Based on our corporate philosophy of "Contribute toward the improvement of people's health and progress in society through the development of innovative products," we will promote sustainable procurement initiatives by incorporating the 10 principles into our operations.

Business Activities

Reliability Assurance

Basic Principles

The Quality & Safety Assurance Division of ASKA Pharmaceutical is responsible for ensuring compliance with the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, as well as the Good Quality Practice (GQP)<sup>1</sup> Ordinance and the Good Vigilance Practice (GVP)<sup>2</sup> Ordinance, ensuring the quality and safety of our pharmaceutical products and supporting a stable

supply. We fulfill our responsibilities based on high ethical standards and a sense of mission so that medical professionals and patients can use our pharmaceuticals with confidence and peace of mind. Our basic policy is to ensure that our pharmaceuticals are manufactured correctly, and to provide information on the proper use of our pharmaceuticals, and as such, contribute to medical care.



**Hajime Asada**  
Director  
Quality Assurance Department  
(Quality Assurance Manager)  
Quality & Safety Assurance Division  
ASKA Pharmaceutical Co., Ltd.

In compliance with regulations including the GQP Ministerial Ordinance, the Quality Assurance Department works to ensure that all company products are of the appropriate quality, through such means as auditing manufacturing sites, assessing the impact on product quality from changes and deviations, and assembling and managing the associated documentation.

Ensuring a stable supply of high-quality products requires diligent efforts not only from personnel at the Iwaki Factory, partner companies’ production sites in Japan and abroad, and other sites directly involved in pharmaceutical manufacturing, but also from members of the production control department, production technology department, Sales Division, and Drug Information Unit, and it is critical that the Quality Assurance Department maintain and build on relationships of trust with all these parties.

To this end, each member of the Quality Assurance Department is constantly engaged in refreshing their knowledge of regulations, which change all the time, and their specialist expertise in manufacturing and testing methods, while also striving to improve their communication and problem-solving skills. Department members also undergo regular GMP<sup>3</sup> audit training and conduct case studies, with a view to meeting the ever-increasing requirements of quality assurance work while enhancing solidarity and collaboration within the organization.

1. GQP: Good Quality Practice  
2. GVP: Good Pharmacovigilance Practice  
3. GMP: Good Manufacturing Practice

Pharmaceutical Information Provision Activities

Basic Principles

The Sales Division is responsible for all of Japan (six regional departments), employing approximately 200 medical representatives (MRs). It provides pharmaceutical information to the physicians and pharmacists who are at the forefront of medical care to ensure that ASKA Pharmaceutical products are used properly. In addition, the company’s head office supports the activities of MRs by providing promotional strategies for each product and MR support information

systems. Even after April 2024 reforms to physicians’ work styles made it increasingly difficult to secure meeting opportunities, we have made every effort to provide proper product information by utilizing a three-pronged approach that effectively fused digital and real-world activities. We are committed to building the best sales force that can meet medical needs that are becoming increasingly diversified by ‘One Step Beyond’ efforts from now on as well.



**Hidenori Hori**  
Director  
East Japan Sales Department  
Region 1  
Sales Division  
ASKA Pharmaceutical Co., Ltd.

The East Japan Sales Department Region 1 is responsible for marketing to medical institutions and pharmaceutical wholesalers in Tokyo and Kanagawa and has a total staff of 44 including 32 MRs as well as managers and administrative personnel. The region includes many university hospitals and associated medical institutions, necessitating information provision of the highest quality. Our mission is to contribute to enhancing the quality of life of women suffering from dysmenorrhea, uterine fibroids, and endometriosis, to enable as many women as possible to perform at their best and lead a vibrant social life.

The physicians and allied health professionals to whom we provide information are extremely busy people who devote their valuable time to meet with us. To ensure that time spent conversing with our MRs adds value to their everyday medical practice, we make it a point to provide state-of-the-art information, including on a wide range of associated diseases. In order to disseminate the latest evidence and guidelines, we also hold frequent online seminars aimed at promoting proper use of our products. These seminars have been extremely well received by the participating physicians and allied health professionals.

By continuing to adhere to compliance requirements while promoting proper use of company products, we aim to help realize a society in which all women can lead healthy and fulfilling lives.

Column: The meaning of animal memorialization

“In an ideal society nothing should be thrown away”

Back in the early Showa Era, when it traded as Teikokusha, the company was engaged in manufacturing foodstuffs and active pharmaceutical ingredients. At this time, the company’s founder, Yasohachi Yamaguchi, decided he could not abide the thought of animal organs being treated as waste (almost entirely discarded with only a little going toward fertilizer production) in resource-poor Japan, and embarked on a journey of mass-producing innovative hormone preparations with a strong commitment to creating valuable medicines from discarded organs. In this manner, the concept of sustainability has underpinned ASKA Pharmaceutical’s operations right from the outset.

In September 1930, Yasohachi Yamaguchi erected an animal-themed memorial tower on the grounds of the Omiya-cho Headquarters Factory (currently Omiya-cho, Saiwai-ku, Kawasaki-shi, Kanagawa), then the company’s main research and production facility. The spirit thus enshrined, namely, that “in an ideal society nothing should be thrown away,” continues to inspire the company to this day.



Inscription on animal memorial tower



Animal memorial tower (Currently relocated to the Iwaki Factory)

Gist of text: *For many years, the Teikoku Hormone Research Institute has manufactured effective pharmaceuticals using animal organs that have been discarded by slaughterhouses. Converting waste into products that contribute to medicine is a momentous achievement akin to turning iron into gold, or a dead serpent into a living dragon, and the very embodiment of the idea that nothing should be thrown away in an ideal society. Moreover, humbly offering up the bodies of animals that have avoided a needless death constitutes an extraordinarily good deed that brings the state of perfect enlightenment sought in Buddhism closer. In the sutra known as the Kegon-kyo, making an offering means letting go of attachments and promising them to the world in a solemn and sacred manner. Animals, too, can part with their beloved bodies, entering the Pure Land and attaining enlightenment.*

Erected by Yasohachi Yamaguchi at the Teikoku Hormone Research Institute on Autumnal Wquinox Day in September 1930.

Respecting Human Rights

Basic Principles

The Group recognizes that it has a responsibility to respect the human rights of all individuals affected by its business activities, in order to help realize a sustainable society. To that end, we pledge to respect human rights based on the Guiding Principles on Business and Human Rights adopted by the United Nations Human Rights Council in June 2011.

In order to fulfill our responsibilities to all stakeholders, the Group supports and respects the international norms and standards listed on the right.

- International Bill of Human Rights (Universal Declaration of Human Rights; International Covenant on Civil and Political Rights; and International Covenant on Economic, Social and Cultural Rights)
- ILO Declaration on Fundamental Principles and Rights at Work (ILO fundamental conventions (core labor standards))
- Conventions pertaining to the human rights of workers including wages and working hours
- United Nations Declaration on the Rights of Indigenous Peoples
- Ten Principles of the United Nations Global Compact
- Declaration of Helsinki (set of ethical principles regarding human experimentation)
- Children’s Rights and Business Principles

Prevention of Harassment in the Workplace

The Group believes that discrimination, harassment, sexual harassment, and power harassment in the workplace are important issues related to human rights violations in the sense that they violate the right to work in a comfortable work environment and are extremely despicable behaviors. To prevent and eliminate such harassment, the Company takes particular care in employment

management and conducts employee training. In particular, the Company ensures that executives and managers acquire accurate knowledge and raise their awareness of harassment prevention through the use of guidebooks and more specific examples in their training on harassment.