

The Japanese Firms Accelerating Medical Innovation

With the oldest and fastest-aging population in the world, Japan's healthcare is facing unprecedented challenges. However, with the help of Japanese ingenuity and innovation, the nation's medical manufacturing companies are taking on these challenges by designing better products, solutions and devices. As the nation moves from treatment to preventive care, new digital technologies such as AI, robotics and Big Data are playing an increasingly prominent role in healthcare, with medical device manufacturers like Toray Medical looking at ways to incorporate these technologies into their products moving forward.

"By utilizing Big Data and AI, the medical industry will be able to provide more high-precision detection and treatment to patients, thus overcoming discrepancies," says Mitsuru Tanabe, President of Toray Medical, whose business includes dialysis equipment, ICU-related solutions, and other medical equipment. "This high-precision and consistent medical treatment will not only be advantageous to patients but also to the government in terms of treatment costs being reduced. Additionally, lower-cost treatment can be done in a shorter period of time."

President of Daiichi Medical, Masaaki Hayashi, also serves as Vice Chairman of the Association of Medical Devices and reveals that within the association, various committees deliberate on the potential for utilizing robots in surgical procedures and other advanced technologies in the medical

field. "We possess the capabilities to implement these cutting-edge technologies," he says, before highlighting Daiichi Medical's own holistic approach to product and technology development. "Our aim is to provide the highest quality and to achieve this, we must consider not only the welfare of patients and healthcare providers but also the broader landscape of social security and healthcare structures. This holistic perspective guides us as we develop new technologies and products."

Meanwhile, in the field of pharmaceutical R&D, PhoenixBio has made groundbreaking contributions such as its mice models boasting 90% human liver cells. "The most significant aspect of our mice is their possession of human liver cells, making them highly effective in combating hepatitis and nonalcoholic steatohepatitis (NASH)," explains President Takashi Shimada. "Initially, our primary focus was on drug metabolism and pharmacokinetics (DMPK) and liver toxicity. However, we also needed to consider the market demand. While the DMPK market is relatively small, hepatitis represents a substantial market with promising opportunities. Furthermore, research on NASH holds potential for further growth."

PhoenixBio has already established a strong global presence through international collaboration – a prime goal for many Japanese firms, including KM Biologics, which was acquired by Meiji Holdings in 2018. "Meiji Seika Pharma has consistently pursued treatments and solu-

tions for infectious diseases, thus maintaining a dominant position in the domestic market. By collaborating with them, we can expect significant synergies in the field of infectious diseases," says Toshiaki Nagasato, President of KM Biologics. "Our strategic vision extends beyond infectious diseases into the fields of oncology and immunology. Additionally, we are committed to leveraging our biotechnological capabilities to develop antibodies. With our expertise in utilizing viruses to develop treatment agents or biotechnology and the technology to produce antibodies using animal cells, we can push forward to pioneer new modalities and generate synergies with Meiji. We want to take on an important role as the pharmaceutical segment of the group."

International expansion is also a priority for Clean Chemical Company, which supplies high-quality cleaning solutions for the medical industry. "Our approach isn't merely about exporting finished products overseas," President Shozo Yano stresses. "It's crucial for us to enter local markets, engage with partners, and leverage our technologies to meet local demands. We aim to find partners who value our expertise, appreciate our support, and collaborate on product development."

He adds: "Our focus remains on high-mix, low-volume production, even as we set our sights on international expansion. We're committed to maintaining our identity as a small company with unique technologies and products."

Japanese Healthcare Leader Looks to Global Markets

KM Biologics boasts a decades-long track record of delivering world-class vaccines, blood-plasma products and newborn-screening services. Now a subsidiary of Meiji Holdings, the company is out to grow its international presence.



KM Biologics HQ, Kumamoto, Japan

KM Biologics plays a key role in safeguarding the health of Japan's population, developing cutting-edge vaccines and blood-plasma products, and screening newborn babies.

"Our company traces its origins to the mission of enhancing public health to bolster Japan's post-war reconstruction," explains President Toshiaki Nagasato.

"In 1945, we began manufacturing a vaccine for the now-eradicated smallpox disease, and we've since become one of only three companies worldwide supplying modern smallpox and monkeypox vaccines."

Mr. Nagasato adds: "After the 2009 pandemic influenza outbreak, we were the first in the world to establish a domestic vaccine supply system – and today we boast the capability to supply the vaccine to around 57 million people."



Vaccine manufacturing process

In the blood-plasma field, KM Biologics' ground-breaking R&D efforts have yielded notable feats such as the development of AnactC, the globe's first activated protein C product derived from human plasma.

Used to treat conditions caused by congenital protein C deficiency, AnactC is one of eight world-first products created by the company.

Since the 1970s, meanwhile, KM Biologics has operated a successful mass-screening program for the early detection of diseases and disorders in newborn children in Japan, with over three million babies tested.



KM Biologics' seasonal influenza vaccine

"Our screening is instrumental in identifying conditions such as severe combined immunodeficiency or spinal muscular atrophy," Mr. Nagasato says.

Acquired by Meiji Holdings in 2018, KM Biologics now aims to leverage synergies with the group's other pharmaceuticals company to grow its international reach.

"We need to be more global," Mr. Nagasato declares. "Meiji



"We want to take on an important role in the pharmaceutical segment of Meiji Holdings."

Toshiaki Nagasato, President, KM Biologics Co., Ltd.

Seika Pharma has established bases in several countries, including China, South Korea, Thailand, Indonesia and India.

"These bases present a significant opportunity to introduce our products into local markets."

Now ideas for wellness

kmb

KM Biologics Co., Ltd.

www.kmbiologics.com

Pioneering Drug Development with Mice Models

Japan's PhoenixBio leads pharmaceutical innovation with cutting-edge mice models boasting 90% human liver cells, helping redefine drug testing globally through a commitment to ethical practices.

In the fast-evolving landscape of pharmaceutical research and development, Japan-based company PhoenixBio is making waves with its groundbreaking contributions to the field. As a contract research organization (CRO), PhoenixBio specializes in providing state-of-the-art mice models with a remarkable 90% composition of human liver cells, setting a global standard for preclinical drug testing.

"This significant proportion of human liver cells distinguishes our product from others, and we take pride in being the only company with such a unique offering," says Takashi Shimada, President of PhoenixBio.

Over the past two decades, PhoenixBio has achieved this remarkable feat via a journey marked by strategic investments and infrastructure development. "Around 20 years ago, we achieved a significant milestone by replacing the organ with human cells, reaching high success rates," explains Mr. Shimada.

"However, to meet the requirements of pharmaceutical companies for proper testing, we had to provide them with a consistent batch of 20-30 animals with unified quality. This led us to establish a facility capable of producing around 4,000 mice annually, which involved substantial investments in both infrastructure and skilled manpower."

The uncertainty surrounding the potential market demand made Shimada apprehensive about the venture, he says. Nevertheless, the company proceeded with the development of its chimeric PXB-mice, which have proven to be invaluable in predicting human body responses and assessing the efficacy of new medications that have not yet reached the market. Consequently, its mice are primarily used for testing drugs under development.

Today, the company's diverse application of mice models range from combating hepatitis and nonalcoholic steatohepatitis to gene-based therapeutics and transplantation. Mr. Shimada asserts, "the most significant aspect of our mice is their possession of human liver cells," making them invaluable for drug metabolism and



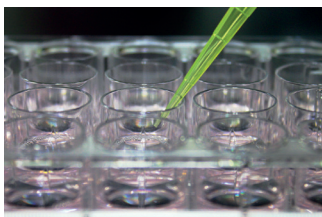
Hiroshima facilities



Clean room



PXB-mouse



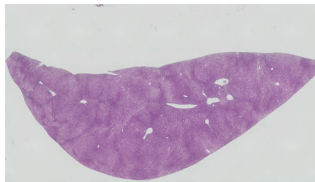
PXB-cells

pharmacokinetics studies. With a focus on international collaboration, PhoenixBio actively engages with researchers and institutes globally, particularly in Europe and the United States.

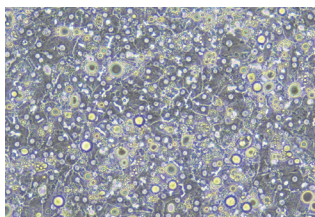
"With a subsidiary in New York City, our fundamental approach remains unchanged," says Mr. Shimada. "Our focus is well-defined with gene-based therapeutics, vi-



Breeding room



PXB-mouse liver



Microphotograph of PXB-cells

ral hepatitis, and NASH being our primary targets. Each of these areas has its own academic community, and we actively participate in relevant academic sessions, engaging with researchers and introducing our products."

Addressing the hot topic of bioethics, Mr. Shimada also discusses the ongoing trend of reducing animal testing and the introduction

of PXB-cells as a substrate for cultivating cells. While acknowledging the shift, he emphasizes the complexity of completely eliminating animal testing, stating: "Ensuring the safety and effectiveness of medicines requires thorough validation, which is difficult to achieve without animal testing."

Going forward, PhoenixBio's international strategy is to enter the European and Chinese markets via two distinct approaches: collaborating with CROs and potential partnerships with specialized sales firms to efficiently reach a wider range of clients. And with already a strong presence in North America, PhoenixBio is also considering expanding its production lines in Canada to better serve the U.S. market.

Mr. Shimada envisions this continued growth by increasing mouse production and finding new customers with a simple yet effective business model that revolves around expanding production capacity to meet the demands of an ever-growing client base.

"We may be categorized as a biotech startup, but at our core, we are primarily a manufacturing company, and our main product happens to be mice," says Mr. Shimada. "Our business model is simple: the more mice we produce, the more we sell. With our production now operating at full capacity, our next step is to increase mouse production further, but this expansion requires finding new customers to purchase these mice. Our growth strategy is founded on the basic principle of producing more to sell more."

As PhoenixBio continues to push the boundaries of preclinical drug testing, its unique mice models stand as a testament to innovation in the pharmaceutical industry. With an eye on international markets and a commitment to ethical practices, the company's journey promises to be a compelling narrative in the years to come.



PhoenixBio

<https://www.phoenixbio.com/>

Toray Medical: Healthcare For Patients Around the Globe



"We will continue to contribute to society by mobilizing our technological capabilities and through providing high-quality, cutting-edge medical products and services."

Mitsuru Tanabe, President, Toray Medical

Since its establishment in 1980, Toray Medical has been committed to offering high-quality medical devices, pharmaceutical products and

Part of Toray Group, Toray Medical combines nanotechnology with biotechnology to develop cutting-edge medical products and services for patients around the globe.

services to patients, as part of its vision to bring the finest-quality and most advanced healthcare to the world.

The company is part of Toray Group, an integrated chemical industry organization developing its business in 26 countries and regions worldwide through combining nanotechnology with its core technologies of organic synthetic chemistry, polymer chemistry and biotechnology.

"Our business began in the blood purification field by offering the world's first synthetic polymeric membrane-based artificial kidney that utilized Toray's fiber technology," says the company president, Mitsuru Tanabe. "Since then, we have developed various products to meet the needs of medical practitioners, including surgical gloves in the surgical



Toraymyxin®

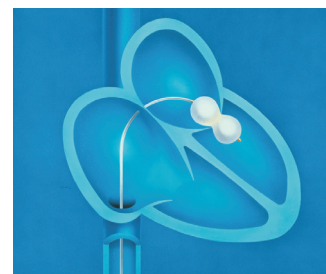
field, catheters in the cardiovascular field, and adsorption columns for emergency treatment and intensive care."

Recently, Toray Medical has also begun offering new products in the minimally invasive IVR (interventional radiology) field. "We will continue to contribute to society by mobilizing such technological capabilities and through providing other high-quality, cutting-edge medical products and services," says Mr. Tanabe.

As a company that operates within the medical industry, it is natural that Toray Medical has a deep respect for Corporate Social Responsibility (CSR), which the company is committed to through prioritizing safety, disaster prevention, and environmental conservation, alongside corporate ethics and compliance through strong and ethical governance.



Toray Filtrizer



"Inoue-Balloon" Catheter

"Through such commitments, we aim to meet the expectations of our customer base of healthcare professionals globally, as well as creating a workplace where each and every employee has a high level of CSR awareness, can hone their skills through their work, and is granted a sense of achievement and fulfillment."



Toray Medical Co., Ltd.
www.toray-medical.com/en

ASKA Pharmaceutical: Revolutionizing Women's Healthcare

In its drive to become a women's healthcare pioneer, ASKA Pharmaceutical is committed to innovation and global expansion.



Head office in Tokyo

ASKA Pharmaceutical is today the leading force in Japan's obstetrics and gynecology sector, showcasing a relentless pursuit of excellence in women's healthcare that demonstrates its commitment beyond mere sales figures. "We aim to become a total healthcare company and a global entity, aligning with our corporate philosophy," says Sohta Yamaguchi, the company's president.

ASKA's strategic shift to a holdings model enables the company to offer comprehensive health



"We aim to become a total healthcare company and a global entity."

Sohta Yamaguchi, President, ASKA Pharmaceutical

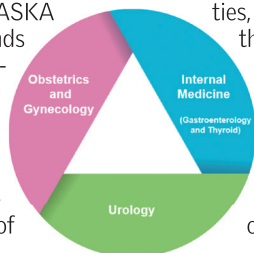
services, from prevention to post-treatment, meeting the evolving needs of a proactive populace. With innovative products like RELUMINA (relugolix) for uterine fibroids and endometriosis, and essential products in the treatment of thyroid disease, ASKA Pharmaceutical stands out by providing effective solutions.

"We offer drugs that provide treatment options for women's health challenges at every stage of life," Mr. Yamaguchi explains. "We aim to not only provide

drugs and treatments but also medical equipment and related services, offering comprehensive health services for females."

And in a world where self-medication is on the rise, ASKA Pharmaceutical sees opportunities, not obstacles. "Over-the-counter options are gaining popularity, and this has led to the growing health consciousness of the Japanese people and the revitalization of the healthcare market," he adds.

Looking forward, Mr. Yamaguchi en-



Three core areas with a focus on pharmaceuticals



Drugs for the treatment of thyroid disease when launched in 1922

visions a future where ASKA expands globally, enriching lives beyond Japan's borders. "By our 105th anniversary in 2025, I hope to report our successful achievements," he shares, hinting at forthcoming advancements in global expansion and new business ventures.

In a nutshell, ASKA Pharmaceutical isn't just about treating ailments; it's about empowering women, fostering health awareness, and pioneering innovations that transcend borders. With Mr. Yamaguchi at the helm, the company's journey towards global leadership in women's health seems not just promising but inevitable.

ASKA Pharmaceutical Co., Ltd.
www.aska-pharma.co.jp

Pioneering Healthcare Innovation: Daiichi Medical's Vision for Transforming Patient Care



"Our mission is to transform healthcare through expertise in ENT and equilibrium, forging a path toward a better world."

Masaaki Hayashi, President, DAIICHI MEDICAL CO., LTD.

In an aging Japan, where the emphasis is shifting towards preventive healthcare, Daiichi Medical stands at the forefront of innovation, with digital technologies being pivotal.

Daiichi Medical is aiming to explore the intersection of medical technology, global expansion, and patient-centered solutions through its ENT treatment for global healthcare excellence.



Frenzel Goggles

With a focus on otolaryngology and equilibrium research, it has pioneered solutions like the ZAOSONiC Ultrasonic Surgical Device and the Diamond Forceps, with an underlying aim of restoring patients' lost functions.

The ZAOSONiC offers the advantage of delicately shaving bone without damaging surrounding tissue, ensuring minimal invasiveness in treatment procedures. The Diamond Forceps can grasp thin and slippery tissues firmly, facilitating precise manipulation during surgical interventions.

"Our aim is to provide the highest quality, considering not only the welfare of patients and healthcare providers but also the broader landscape of social security and healthcare structures," says company president Masaaki Hayashi. A portable device for Meniere's disease garnered recognition, testament to the firm's QOL dedication to patient-centric innovation.

Amid decisive efforts to increase its international presence, navigating the challenges in adapting to different healthcare systems, the company is now targeting the likes of Australia, India and Saudi Arabia for growth.



Diamond Forceps



Ultrasonic Surgical Device

"We would like to change the world with our unique ENT devices and expert staff," Mr. Hayashi concludes, envisioning a future that echoes Daiichi Medical's commitment to transforming lives.

ENTFirst
www.first-med.co.jp

Clean Chemical Company: 50 Years Contributing to Precision in Cleaning Medical Equipment

Pioneering safe, sustainable and high-quality cleaning solutions for the medical industry.

First established in 1975, Clean Chemical Company is an industry leader with advanced product development capabilities and products that provide optimal solutions for its customers.

According to company president Shozo Yano, the firm's strength lies in meeting its clients' diverse needs: "We provide safe, high-quality products and services by employing advanced technologies in controlled environments."

Faced with growing challenges related to Japan's aging population and shrinking domestic labor market, Mr. Yano is also keen to emphasize how the firm invests in its existing personnel.

"We nurture our employees' skills and capabilities," he says, "putting money into resources to support their professional development. We provide additional



"Innovation is our legacy, excellence our commitment, and meeting diverse needs our driving force."

Shozo Yano, President, Clean Chemical Co., Ltd.



Takatsuki Core Center

training, educational opportunities, and involvement in diverse projects to encourage growth and skill-building."

"Our focus," he continues, "is not on exporting finished products to



Laboratory

overseas markets, but rather on establishing OEM collaborations."

Partnerships, in other words, are vital. "It's crucial for us to enter local markets," Mr. Yano confirms, "engage with partners

and leverage our technologies to meet local demands. We highly appreciate partners who value our expertise, appreciate our support, and collaborate on product development."

The company has obtained the ISO/IEC 17025:2017 laboratory accreditation standard from Perry Johnson Laboratory Accreditation Inc. for its analysis of residual protein in cleaned medical instruments, a development that should enable the company to expand globally.

Equally important, however, is the company's focus on high-mix, low-volume production, and maintaining its identity as a firm like a small but agile yacht with unique technology and products.

CLEAN
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