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《Dialogue》 SPECIAL TALK

Takashi Maeno × Kazuo Nakamura

Achieving well-being beyond
the concept of health in
an era of 100-year lives

03 ((Dialogue)) SPECIAL TALK

Takashi Maeno

Professor, Graduate School of System
Design and Management
Keio University
Wellbeing Research Center Director



Kazuo Nakamura

Representative Director,
Chairman and CEO
CIMIC HOLDINGS Co., Ltd.

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Theme of the Cover:

A city in winter with snowfall. People are attempting to communicate by drawing on clean snow. But it seems that it's not quite as good as they thought. The theme of the cover illustration is "changing perspectives." It is commonplace for each person to have a different interpretation despite seeing and hearing the same thing. So making consistent efforts to communicate in order to reach the same perspective is very important.

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What is C-PRESS?

The "C" of C-PRESS refers to the "C" of CMIC and the "C" of communication. C-PRESS is CMIC Group's public relations bulletin, which presents corporate activities and business lines of the Group centered on topics in the medical and healthcare fields.



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Achieving well-being beyond the concept of health in an era of 100-year lives

While Japan has one of the longest life expectancies in the world, it ranks #58 out of 156 countries in the World Happiness Report ¹⁾, indicating that longevity does not necessarily correlate to happiness.

What do we need to live happily?

CEO Nakamura interviewed Professor Takashi Maeno of Keio University, who has carried out a wide range of studies—on approaches to “well-being” as well as to “happiness”—in order to search what needs to be done to build a society where each person can achieve well-being.

Shifting from engineering to well-being

Nakamura: When I first heard about your studies, I was very impressed with how you adopted a completely different approach toward reaching the concept of “well-being,” which CMIC have been embracing as a key since our foundation. To start, can you tell me how you came to study well-being?

Maeno: I was originally an engineer. I worked for a camera manufacturer after studying mechanical engineering in college. When I became a professor, I devoted myself to studying robots in an attempt to reproduce the human spirit. However, although robots have gradually come to more closely imitate the human body, they are barely able to feign the spirit. I then came to realize that I have been studying humans themselves by having robots mimic them, which strongly motivated me to deepen my understanding of the human spirit.

“Well-being” is a broad concept that encompasses happiness, health, and welfare; it is concerned with the fundamentals of the human spirit. At present, however, the concept of well-being is missing from all social structures and products. This inspired me to adopt an engineering perspective to incorporate well-being into design methodologies across all aspects, including products, services, organizations, and cities.

Nakamura: In my case, my experiences during my college years when there was a wave of campus disputes convinced me to create new things with my hands, which is like creative destruction. At the same time, my college was in Kyoto, and seeing the graves of historical figures scattered about

the temples and such made them feel more familiar as well as led me to realize that death is inevitable for all of us. Even after I joined a pharmaceutical company, I always thought about how I should live in the present if I cannot avoid death, as well as what happiness really is in a society where people live longer. That’s when “well-being” came to be my conclusion. I believe that well-being is about making the best effort to always improve, no matter what the outcome may be. Well-being was incorporated into CMIC’s corporate culture upon its foundation, and that spirit remains unchanged.

Establishing well-being as a practical academic frameworks

Nakamura: Your approach of upgrading well-being into a study system is unique and striking. Can you walk me through the details?

Maeno: Well-being is the state of having health, happiness, and welfare. While health is covered by medical science and welfare is covered by welfare studies, the academic landscape for happiness has not matured. Of course, basic research on psychology advances day by day, but I’m an engineer and envision that insights unraveled by science contribute to society and help people. For that to happen, I came to believe that a new framework that takes an interdisciplinary approach to well-being should be established.

Nakamura: Indeed, well-being must be tackled as an interdisciplinary issue. In addition to “happiness,” it seems the word “healthy” has also begun to deviate from actual circumstances in the era in which we live, where people live more than 100 years. If being “healthy” is defined as

having normal health check results, I’d say that most people in their 80s are not healthy. But as I mentioned earlier, people face death eventually, and from this perspective, aging is just a natural phenomenon. That said, each age group and individuals have their own set of “well-being” in terms of physical health. I believe well-being must be positioned as the dominant conception of health.

Maeno: Absolutely. I believe that in addition to medical science and psychology, business administration, economics, engineering, and pharmaceutical sciences, should be systemized as applied studies of well-being.

The 4 factors for happiness

Nakamura: Recently, Japan’s concept of “IKIGAI” (reason for being) has been attracting attention around the world. There have also been studies reported in which people who feel *ikigai* by committing to society and receiving remuneration live longer than those who do not feel *ikigai*. It is very encouraging and delightful to see that studies on well-being are now being systemized in Japan, where the wonderful concept of *ikigai* exists. I presume that the “four factors for happiness” derived from your sophisticated engineering methodologies are strongly associated with *ikigai*. Can you tell me in detail about these four factors? ²⁾

Maeno: Through a method called factor analysis, I researched studies and statistically compiled data regarding happiness all over the world, and by systemizing them, came to discover the four factors that are keys to achieving

happiness. I named them as follows: “I’ll give it a try!” “Let’s have it as it is!” “It’ll work out!” and “Thank you!” Fulfilling these factors will create happy companies, cities, and societies. The senses of fulfillment and *ikigai* fall under the first factor, “I’ll give it a try!”. Studies show that people who feel *ikigai* are happy and live long. In that sense, there is a strong connection between well-being, happiness, and *ikigai*.

Nakamura: Despite having such a wonderful concept of *ikigai*, Japan ranks very low in the World Happiness Report. Why is this?

Maeno: There are two reasons. The first is due to a problem with the measurement method. The World Happiness Report ranks the level of happiness by asking respondents to score their lives on a scale of 0 to 10, with 0 being the worst and 10 being the best. In countries with a stronger sense of collectivism, more respondents will give scores of “5.” But in countries where individualism prevails, respondents are more inclined to subtract points from the maximum of 10, so there are more scores of “8” and “9.” In Japan, there are two peaks around the scores of “5” and “8.” This merely reflects Japan’s current condition in which collectivism and individualism are mixed; this differs from the country’s level of happiness. Nonetheless, as demonstrated in objective indicators such as the low level of self-affirmation and high suicide rate, it is a fact that Japan has a rather low level of happiness. This must be taken seriously. In order for Japan to survive in

The 4 factors for happiness



Nakamura Kazuo



Maeno Takashi



international society, it is crucial to restore its spirit of mutual assistance in addition to *ikigai*.

Nakamura: Upon seeing and hearing the words and actions of disaster victims, I still feel the spirit of mutual assistance remains deep in the hearts of the Japanese. It is moving and I feel that Japanese are blessed when seeing people appreciate one another while accepting their helplessness against the powers of nature. Viewing the level of happiness in this sense, Japan may be quite a leader.

Maeno: As you point out, the level of happiness is currently measured by asking respondents how happy they feel, so it is one-sided. The concept of “collective happiness” has recently been suggested, and efforts are underway to develop a multifaceted scale for measuring happiness that also incorporates factors such as mutual assistance.

Happiness rooted in Japan's nature

Nakamura: In addition to happiness based on collectivism, it is also

important to respect and encourage diversity in each individual. However, it seems that the educational structure for fostering individuality is still underdeveloped, given the low level of diversity among educators and the lack of personnel.

Maeno: Originally, Japan has shown an inclination for collectivism, but given that individualism has also gained stature recently, the strengths of collectivism, which encourages mutual assistance, and the benefits of encouraging uniqueness from individualism, are not working together. I think that this has led to the country's decline in well-being.

Nakamura: In addition to having a collectivism-oriented culture, Japan also has a culture of individualism, exemplified by its people independently interpreting the stories depicted by the four seasons and nature. The sophisticated plots of Japanese anime that receive accolades are another part of this culture. By contrast, Disney movies depict rich emotions even for animals, and I feel that human emotions are vividly portrayed.

Maeno: In fact, the quality of emotions

that Japanese anime and Disney movies stir up is quite different. According to my analysis of how audiences were moved, *Frozen* was rather monotonic, while *Spirited Away* had multiple frames that moved the audience, and these differed by the individual. I think this is what makes Japanese culture profound.

Nakamura: Japan is among the countries that experience the most natural disasters. However, in the same way that volcanic ash cultivates land to underpin agricultural culture, I think that disasters have played a part in fostering Japan's culture, which stays close to nature. In a sense, this is Japan's interpretation of happiness.

It would be truly wonderful if this spirit that is deeply rooted in Japanese culture could be translated to product development and organizational establishment.

Maeno: Japan's long-standing history amid frequent disasters is proof of sophisticated sustainability. Because many notable cultures and traditional arts remain throughout the country, Japan will be greatly enriched if it can leverage these excellent qualities scattered nationwide while incorporating the benefits of Western-style centralization.

Achieving a society that improves one another's well-being

Maeno: Through my research, I reached the conclusion that well-being is a condition in which all members of society have their own *ikigai* and maintain appropriate connections with other diverse members. Here, it is important to receive some form of remuneration and appreciation while

having a sense of trust, *ikigai*, and connection with others—in other words, a “sense of purpose.” Our challenge is how to create a society to actualize this.

Nakamura: Particularly in corporate organizations, how to structure teams and otherwise combine people is critical for maximizing individual potential. What are your thoughts?

Maeno: Actually, this field is my current interest. We are currently capable of measuring happiness from a multifaceted approach by incorporating extroversion and optimism, so applying this method can measure an organization's level of happiness. This method can also be applied to families, and we were just about to start surveys on the happiness of life and work for both the company and the family.

Nakamura: Humans are creatures that live in groups after all, so such a perspective is important. Also, I think art is another important element for humans.

Maeno: Yes, art has a very strong correlation with well-being. In addition to aesthetics, art also refers broadly to activities that enhance sensitivity and deepen our understanding of beauty. Art taken in this wide sense is known to improve well-being.

Nakamura: Art in Japan is tremendously extensive, ranging from the simple beauty represented by *wabi-sabi* to extravagant armory. Still, both ends are rooted in nature. This is why I find Japanese artistic sensibility to be truly marvelous.

Maeno: Culturally, Japan has been influenced by China and India, and post-war by Western culture. However, it is remarkable that while accepting all these influences, Japan maintains its own tastes at its core.

Nakamura: Meanwhile, although it is a fact that the Japanese are not generally

interested in promoting diversity, acceptance of diversity will push forward a culture that respects others' opinions, which will in turn enhance mutual well-being.

Lastly, what are the issues that must be tackled in the study of well-being, and what is such study's impact on society?

Maeno: To have well-being firmly take root, society as a whole must shift towards focusing more on social capital and a spirit of mutual cooperation, instead of solely on money. I plan to establish research and educational sites for well-being based on industry-government-academia collaboration.

Nakamura: From a pharmaceutical standpoint, CMIC is working to build a foundation to help improve well-being as the dominant conception of health, including developing methods that go beyond use of pharmaceuticals. Thank you for joining me today.

PROFILE

Takashi Maeno

Professor, Graduate School of System Design and Management
Keio University
Born in Yamaguchi, Japan, in 1962. Dr. Maeno received his B.S. and M.S. degrees in mechanical engineering from the Tokyo Institute of Technology. After completing his Master's, he worked for Canon, Inc. at the Production Technology Research Center. Before obtaining his current position in 2011, he was a visiting researcher at the Department of Mechanical Engineering, University of California, Berkeley and Professor in the Department of Mechanical Engineering, Keio University. He received his Ph.D. in mechanical engineering from the Tokyo Institute of Technology in 1993. Dr. Maeno conducts research on various types of system design and management, including human interface design, robots, education, local communities, business, happy lives, and world peace.



- 1) Helliwell, J.F. Et al, World Happiness Report 2019
- 2) Takashi Maeno (2013), Mechanism of Happiness: Introduction and Practicing the Study of Happiness, Kodansha's New Library of Knowledge

Initiatives by the Japanese Society for Inherited Metabolic Diseases to Introduce Rare Diseases Drugs to the World

An issue for many drugs used to treat rare diseases is that there used to be many drugs that remained undeveloped and unapproved in Japan as very few patients required them, despite their use as standard drugs outside Japan. The number of such unapproved drugs was particularly large in the pediatric field.

Dr. Toshihiro Ohura, the Assistant Director and the Head of the Pediatric Department of Sendai City Hospital, who has addressed the issues of unapproved drugs in the area of inherited metabolic diseases as the Chairperson of the Pharmaceutical Affairs Committee of the Japanese Society for Inherited Metabolic Diseases (JSIMD) for a long 15 years since 2004, talked about these issues.

Situation 15 Years Ago —Early Days of Orphan Drug Development

One of the roles of the JSIMD Pharmaceutical Affairs Committee is to promote the proper use and steady supply of drugs. When I became the chairperson of the Committee in 2004, most therapeutic drugs for inherited metabolic diseases were not yet approved in Japan. We had to import these drugs privately or use Japanese drugs produced for experimental purposes to treat affected patients. Even if drugs were available, there was a need to increase the number of indications for these drugs as their approved indications were limited. When privately-imported drugs or experimental drugs were used, they were prescribed after obtaining written consent from the legal guardians of pediatric patients, and there were no public relief systems for sufferers from adverse reactions to such drugs. Under these circumstances, we felt a pressing need for officially approved drugs.

Inherited metabolic diseases are medical conditions caused by some abnormality in metabolic processes, interfering with the body’s metabolism from birth. Most of these diseases are rare, affecting very few people (from several to several hundred in number) in Japan. The small market size and poor potential sales, compounded by the high expected development costs, meant that pharmaceutical companies were unwilling to develop therapeutic drugs for inherited metabolic diseases. Meanwhile, clinical trials of drugs for rare diseases (i.e., orphan drugs) had started around this time, and some of such orphan drugs were launched in the market. Development on new orphan drugs was also beginning in the US, and in hopes of making these new drugs available quickly in Japan, the public drew its attention on orphan drugs.

Development at a Standstill for Unapproved Drugs

The Ministry of Health, Labor and Welfare (MHLW) convened “Review conference of Unapproved Drugs Use Issue” in 2005 to resolve the issue of unapproved drugs. The committee also started to investigate drugs that should have begun development earlier in Japan. The JSIMD Pharmaceutical Affairs Committee conducted a questionnaire survey on the members of JSIMD and submitted a list of drugs and a request to the MHLW, in order to address the necessity of prompt development of unapproved drugs. The MHLW then had to wait for pharmaceutical companies to take the results of the Special Committee’s investigations and develop the drugs needed by request from JSIMD. Despite these activities, few pharmaceutical companies began the development of these drugs, and the issue of unapproved drugs remained unaddressed for several years.

Under such circumstances, JSIMD made efforts to proceed with development plans by performing multicenter clinical studies to confirm the efficacy and safety of some drugs.



The Turning Point

The Review conference of Unapproved Drugs Use Issue was reorganized into a new special committee, “The Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs” in 2010 to address wider issues related to unapproved drugs and Off-label use of drugs in all medical fields, especially pediatrics. The MHLW then makes requests or open calls to related companies to develop drugs considered by this new Special Committee to have a high medical need. Since then, development of unapproved or off-label drugs has accelerated.

In addition, a new pricing system “Premium to promote the development of new drugs and eliminate off-label use” was introduced in 2010, which helped make pharmaceutical companies become more actively involved in the development of novel orphan drugs. With this Premium System, MHLW gives preferential treatment when revising drug prices to companies engaging in the development of drugs requested or answering the open call by MHLW, as well as companies involved in research and development of drugs contributing to the enhancement of medicine quality.

Drugs That Have Become Available

With the help of the Premium System, more and more pharmaceutical companies began to work actively on the development of orphan drugs, and even new companies focusing on or dedicated to the development of orphan drugs began to appear. Some drugs that have been in demand for years by patients and JSIMD have finally become available. The table below lists the main drugs for which I was directly involved with as the chairperson of the Pharmaceutical Affairs Committee and which were eventually approved. A number of other orphan drugs were approved in addition to the drugs listed here. Furthermore, yet more drugs are currently being developed or

have open calls for their development. Meanwhile, JSIMD continues to request the development of unapproved drugs of high medical need. Approval of drugs is not our ultimate goal. JSIMD is working on the proper use of approved drugs. For example, after sapropterin hydrochloride was approved for an additional indication, JSIMD established the Special Committee on Diagnosis and Treatment of BH4-responsive Hyperphenylalaninemia and prepared interim guidelines for proper use of the drug to raise user awareness. During the annual JSIMD conference, a BH4-related Committee Debrief Session was held to exchange information.

Table: Approved Drugs Used for Treatment of Inherited Metabolic Diseases

	Drug (generic name)	Indication requested to be approved	Date of approval
1	Sapropterin hydrochloride	BH ₄ -responsive hyperphenylalaninemia (additional indication)	Jul 2008
2	Levocarnitine chloride	Carnitine deficiency (additional indication) (Additional dosage form: liquid; intravenous injection)	Mar 2011 Dec 2012
3	Miglustat	Niemann-Pick disease type C	Mar 2012
4	Sodium phenylbutyrate	Urea cycle disorder	Sep 2012
5	Betaine	Homocystinuria	Jan 2014
6	Cysteamine bitartrate	Nephropathic cystinosis	Jul 2014
7	Nitisinone	Tyrosinemia type 1	Dec 2014
8	Carglumic acid	NAGS deficiency, isovaleric acidemia, methylmalonic acidemia, propionic acidemia	Sep 2016

BH₄: tetrahydrobiopterin, NAGS: N-acetylglutamate synthetase

Various Activities of JSIMD to Support Patients with Rare Diseases

Making unapproved orphan drugs available in Japan is one of the JSIMD’s roles. Our other roles include the establishment of diagnostic criteria for designated intractable diseases and treatment guidelines for standard treatment of patients with such diseases. JSIMD submits petitions to designate certain diseases as intractable diseases so that affected patients can receive public assistance. JSIMD also works on the stable supply of special milk formulas that are indispensable for treatment. In recent years, one novel drug after another for inherited metabolic diseases have been developed. It is desirable to start

treatment before symptoms progress, so early detection of a disease has become increasingly important. JSIMD has reported the results of studies on new target diseases for mass newborn screenings to enhance early detection/diagnosis of treatable diseases.

Here, I have talked mainly about the initiatives by the JSIMD Pharmaceutical Affairs Committee regarding the issues of unapproved drugs and off-label drugs as well as the background of their development. I hope that this was of help in the future development of orphan drugs.

Contract Formulation Development and Manufacturing Services

Contract Development and Manufacturing Organization (CDMO)

Following changes in the value chain for pharmaceutical development, businesses that assist in developing and manufacturing pharmaceutical formulations are increasing their presences. Executive Officer and Business Development Director Murakami will explain the features and strengths of CMIC Group, which operates such a business.



Hideki Murakami
Executive Officer and Business Development Director
CMIC CMO Co., Ltd.

Photo: Katsumi Kurihara

▼ Features of the CDMO business related to formulation development

Developments ranging from the discovery of pharmaceutical seeds to the manufacturing and marketing of products are now quickly growing in demand at more advanced levels. Following this, pharmaceutical companies have increasingly outsourced many development processes. Among these, CDMO is responsible for formulation development and product manufacturing.

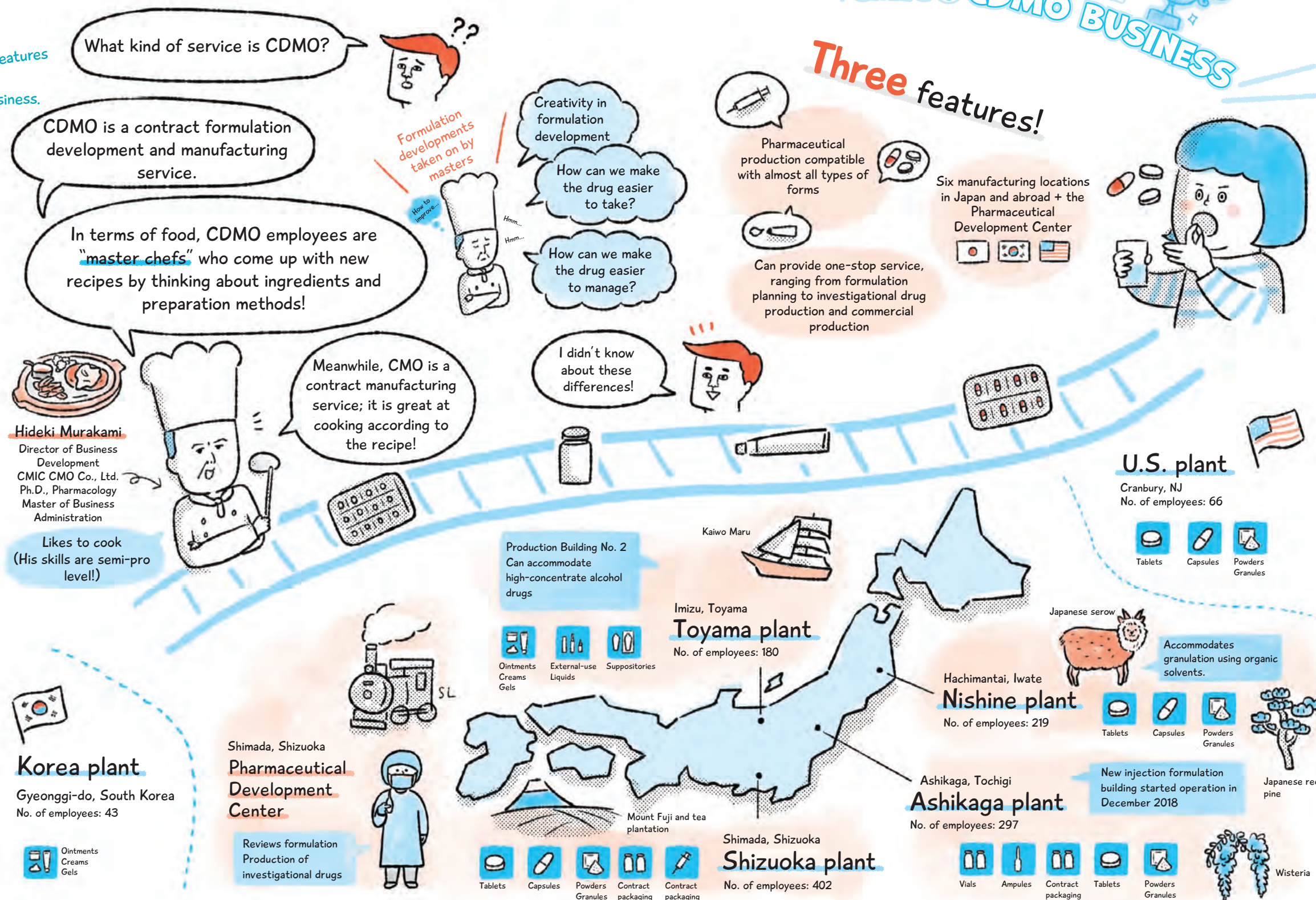
To accelerate launch pharmaceutical products, though it is important to design substances discovered as seeds into formulations, conduct clinical trials, and proceed smoothly to mass production, we also assist in achieving rapid development by taking responsibility for the designing and manufacturing of new clinical drugs used in clinical trials. This feature sets us apart from conventional CMO services that only manufacture, and also demonstrates a strength of CMIC Group, which runs clinical development operations in addition to CDMO.

To describe this in terms of cooking, CMO is a chef that cooks by following recipes, while CDMO is a "master chef" who comes up with new recipes and cooks.

▼ 6 plants in Japan and abroad capable of producing a broad variety of formulations


CMIC Group has 4 plants in Japan and 2 plants overseas; it can produce virtually any type of form for solid agents, semi-solid agents, and injections. Furthermore, its employees possess sophisticated techniques, knowledge, and sound ethical standards; they are devoted to manufacturing products of exceptional quality. Meanwhile, the Pharmaceutical Development Center in Shizuoka can handle processes leading to formulation, including formulation design, scaling up, and stability confirmation in order to manufacture a diverse array of investigational drugs.

Thus, CMIC Group is one of very few CDMO companies that can develop formulations and manufacture investigational drugs as well as commercial products.



Signed a joint research agreement with Keio University:

— Will work to improve well-being (health and happiness) and promote work style reforms




SDM
System Design and Management

Graduate School of System Design and Management
Keio University

Research contents

Improve user's well-being by utilizing the PHR (Personal Health Record) system "harmoni"



CMIC Group

Develop a well-being educational program that promotes work style reform

CMIC Holdings entered into a joint research agreement with Keio University effective November 13, 2019 to improve well-being (health and happiness) and to promote work style reform. In this joint research, CMIC Group, which strives to improve each person's health value through its healthcare business, will engage in research and development by collaborating with an academic institution, namely Keio University on this project. The research team is led by Professor Takashi Maeno of the Graduate School of System Design and Management, Keio University, who jointly serves as Director of the Keio University Wellbeing Research Center. He conducts various studies on happiness.*

* Studies to research the "mechanism of happiness" in humans using psychology, statistics, and scientific approaches

Presented the CMIC Award at the 33rd Japanese Society for AIDS Research Conference



CMIC presented the CMIC Award at the 33rd Japanese Society for AIDS Research Conference and General Meeting held from November 27 at Kumamoto-jo Hall to Dr. Tetsuro Matano, Director of the National Institute of Infectious Diseases, AIDS Research Center, for his achievements in HIV-related research.

The CMIC Award is presented annually to a member of the Japanese Society for AIDS Research (No. of members: approx. 2,000) who has contributed to the academic society's advancement through his or her achievements related to HIV and achieved original, remarkable results. The award was presented to the 16th recipient this year.

As a company that excels in promoting women, CMIC has achieved the highest L-Boshi Certification

CMIC Co., Ltd. received the L-Boshi Certification, with the highest level of the three-point, from the Ministry of Health, Labour, and Welfare for all five evaluation items: "hiring" "continued employment," "working hours," "managerial position ratio," and "diverse career paths."



In addition to the company's unique systems for childcare leave that incorporate flex-time, telework, shortened work hours, and care leave, CMIC has been developing a flexible, adaptable system to make workplaces more welcoming for employees with various backgrounds, such as offering the option of limiting field work for employees before and after maternity leave and childcare leave to areas close to their homes.

CMIC also works to build an environment in which all employees, including men and women, can demonstrate their capabilities to the fullest by offering childcare leave for male employees and nursing leave.

CMIC selected for "This is MECENAT 2019" certification

The Nakamura Keith Haring Collection International Children's Drawing Contest, run by the CMIC Group as one of its social contribution initiatives, was certified as "This is MECENAT 2019" by the Association for Corporate Support of the Arts.

The Nakamura Keith Haring Collection International Children's Drawing Contest is the only international drawing competition in the world for children approved by the Keith Haring Foundation; it passes down Keith Haring's devotion to promoting hope for the future, love, and peace to children. The contest is held annually and co-hosted by the Nakamura Keith Haring Collection and CMIC Group.

Through these activities, CMIC group provides opportunities for children to understand different races, religions, cultures, and environments in the world in order to strive for a global society with liberty and to broadly contribute toward the betterment of society.



RDD : Rare Disease Day CMIC sponsors RDD, Rare Disease Day 2020

Have you heard of Rare Disease Day (RDD)? Held on the last day of February each year, RDD is observed to improve the quality of life for patients with rare and refractory diseases. CMIC Group has taken part in this day since 2017. Through RDD events intended to deepen understanding of rare and refractory diseases among as many people as possible, CMIC, with the hope of serving as a bridge between patients and society, will continue to support this day so that such diseases become better recognized by medical professionals and society as a whole.



A new company to strengthen CMIC's healthcare business

CMIC Healthcare Institute Co., Ltd.

SMO
(Site Support Institute)

To merge
January 2020

Healthcare Business
(CMIC Healthcare)

In January 2020, Site Support Institute Co., Ltd. and CMIC Healthcare Co., Ltd. will merge to start anew as CMIC Healthcare Institute. By joining hands, SSI's various insights and knowhow accumulated through its SMO business and CMIC Healthcare's data on disease prevention and health as well as IT will synergize, setting it apart from the rest in order to accelerate the development of CMIC Group's healthcare business.

