



2018

Towards the Development of the Life Sciences Industry

Special Feature

Immunotherapy and Regenerative Medicine in Osaka, Kansai

Osaka Bio Headquarters

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Strive to create a new hub capitalizing on the strengths of OsakalKansai

such as regenerative medicine.

Background

After the adoption of the "system of approval with conditions and time limitations" in the revision of the Pharmaceutical Affairs Law in 2014, Japan has created an environment to lead the world in regenerative medicine. Furthermore, institutions in

Osaka/Kansai such as Osaka University, Kyoto University, and the Riken Institute of Physical and Chemical Research are conducting advanced research as top runners in the world.

Under such circumstances, we aim to create an international hub for cutting-edge medicine (Medical Innovation) in Nakanoshima which adapts to advancements in future medical technologies based on regenerative medicine such as the utilization of genome medicine, Al, and IoT.

Open in 2021

Nakanoshima, where the International Hub for **Medical Innovation is scheduled to be created**

Nakanoshima is a major business district in Osaka as well as a hub for the transmission of culture and information featuring international conferences, art museums, etc. A station is scheduled to be built there on the new line which will connect directly to Kansai International Airport, the gateway to Osaka/Kansai (operation will start in 2031), and access from overseas will be strengthened with that.



The concept and vision of the hub

Development of Medical Innovation







- Realization of open innovation bringing together businesses, academia, and
- ©Support for companies entering the field of regenerative medicine
- ©Development of international cutting-edge research projects
- ©Establishments of standards for inspection, etc. toward productization
- ©Formation of high-quality big data and its application to genome and preemptive medicine
- OPromotion of clinical research and clinical trials

Implementation



The promotion of Medical Innovation

- The practice of cutting-edge medicine which is devel-
- OInternational contribution through the promotion of inbound/outbound of cutting-edge medicine
- Overseas expansion of developed products and schemes,
- ©Cutting-edge examinations and prediction diagnostics
- OTraining of advanced specialists





Medical institution OOResearch PJ Medicine utilizing Al ◆◆Research PJ medicine Individualized HOSPITAL ○ University medicine **♦♦**University OODoctor **♦**◆Doctor Company ○ Company **♦♦**Company Academia **Promotion of regulatory** Training of advanced professionals ★★Research PJ □ Research PJ **★★**University □ □ Research Lab **★★**Doctor □□Fellow Regenerative medicine and Medicine-engineering **★**★Company □ □ Company other products collaboration **Japan Agency for Medical Research and Development (AMED) Department of Innovative Drug Discovery and Development**

Pharmaceuticals and Medical Devices Agency (PMDA) Kansai Branch

National Center for Industrial Property Information and Training (INPIT) Kansai Office

Provision of solutions to companies and patients

Businesses, academia and medical institutions all coming together to construct a platform to contribute to solving problems for companies and patients. Provision of one-stop solutions.

An international hub open to the world making consistent advancements from clinical research into Medical Innovation to its implementation and industrialization

Gathering of Osaka's life science related universities and research facilities, etc.

Osaka has been known as "a town of pharmaceuticals" since about 400 years ago.

With many excellent life science related universities and research facilities, etc., in northern Osaka, Pharmaceutical

companies, etc. are also gathering in places like Saito(International Culture Park) and Doshomachi in Osaka City.

Saito(International Culture Park) and Doshomachi in Osaka City.

In Osaka, industry, academia and government are working toward further development such as gathering

drug discovery support agencies in Ume-Kita in central Osaka,

regarding life science field as one of our strengths.

Osaka has a good business environment so that you can develop life science related business easily here.



2016 Japanese pharmaceutical company sales ranking

Domestic World

1st(17th) Takeda Pharmaceutical Company Limited.

2nd(20th) Astellas Pharma Inc.

3rd(25th) DAIICHI SANKYO COMPANY, LIMITED.

4th(26th) Otsuka Holdings Co.,Ltd.

5th(31th) Eisai Co.,Ltd.

6th(35th) Chugai Pharmaceutical Co., Ltd.

7th(39st) Mitsubishi Tanaba Pharma Corporation.

8th(42th) Sumitomo Dainippon Pharma Co., Ltd.

9th(45th) Shionogi & Co., Ltd

10th(48st) Kyowa Hakko Kirin Co., Ltd

11th(53th) ONO PHARMACEUTICAL CO., LTD.

12th(61nd) Santen Pharmaceutical Co., Ltd.

13th(65th) Nichi-Iko Pharmaceutical Co., Ltd.

14rd(72th) Meiji Seika Pharma Co., Ltd.

15th(74rd) Sawai Pharmaceutical Co.,Ltd.

Companies colored in yellow have a head office in Osaka / (): world's ranking.

(Source)KEN Pharma Brain, New Pharma Future VOL. 2 No. 7, 2017



Symbol zone of Saito spreading in the hills of Ibaraki City, Minoo City, Osaka Prefecture

みどりとみらいのみえる丘

Saito Life Science Park

Saito Life Science Park that came up in 2004 is a major base of facilities having research and technology development functions in various life science fields such as biotechnology-based pharmaceuticals, food items, cosmetics, and healthcare related facilities association with the same.



Incubation facilities Saito Bio Incubator Saito Bio Hills Center Saito Bio Innovation Center Structure:Steel beam, 4-story Structur:steel beam, partially rejuforced Structure:Steel beam, 4-story Total floor:approx 2.500 m Total floor:approx 4,900 m concrete. 3-story and one basement floor 3rd floor: approx. 800 m² Lab:32rooms+1 floor _ab:18 rooms+1 floor There are Animal experimentation facility Lab:10rooms There are investigational drug manufacturing facility Maintenance: Maintenance: Organization for Small & Maintenance: Organization for Small & YASHIMA PURE CHEMICALS CO..LTD. Medium Enterprises and Regional Innovation Medium Enterprises and Regional Innovation Public-private rental lab Public-private rental lab Public-private rental lab Established:2004 July Established:2006 April Established: 2008 October Rental grants: facilities grant system.



An illustration of the Nucleic Acid Medicine API Development Center

Voice of a company located in Saito

GeneDesign, Inc.

Quickly noticing the development of nucleic acid medicine which has been gathering attention as a next-generation medicine, in 2010 they developed the nation's largest nucleic acid investigational new drug manufacturing facility in Saito Bio-Innovation Center, and obtained the license for the production of nucleic acid medicine in Japan. In 2013 they established "Nucleic Acid CMC Research Center", the first nucleic acid medicine related research center in Japan within the Saito Life Science Park. In 2016 they merged with Ajinomoto Group, which they had been advancing joint research with for some time. In 2019 they are planning to open the "Nucleic Acid Medicine API Development Center" as a base for the large-scale production of nucleic acid medicine. CEO Yuyama states: "Research universities and research institutions from around the country have gathered

CEO Yuyama states: "Research universities and research institutions from around the country have gathered around Saito, enabling the acceleration of development in industry-academia-government projects. We were certified as a special zone business and allowed to receive funding support. Through the completion of the new base we hope to meet the demand for nucleic acid medical products which will grow in the future."

"Saito Hills Club" is also available as a place for information exchange, research exchange, human exchange, etc. of companies and research institutes around Saito. For inquiries regarding incubation facilities, please contact Bio · Site · Capital Co., Ltd./TEL.+81-72-640-1060/URL http://www.bs-capital.co.jp/

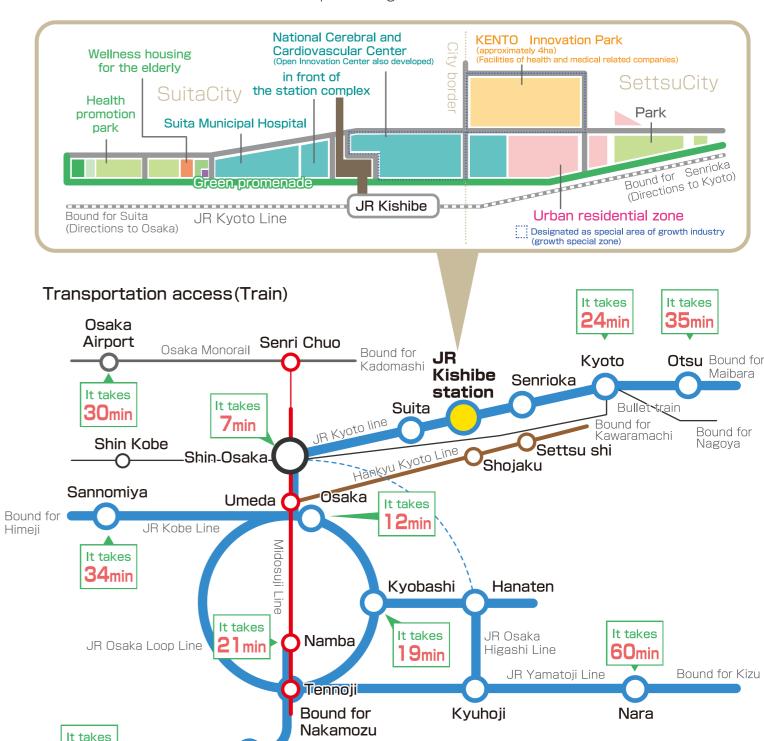
Town of "health and biomedical"

Northern Osaka Health and Biomedical Innovation Town (KENTO)

KENTO (approximately 30ha), where the creation of health and medicine hubs is proceeding, focusing on the National Cerebral and Cardiovascular Center which will start operations from July 2019 and the National Institute of Health and Nutrition which has established a policy to be relocated there from Tokyo.

It has excellent transportation access because of its proximity to Umeda and Shin Osaka.

As health and medicine related facilities steadily increase, we are planning for research facilities, etc. such as health and medicine related companies to gather in KENTO Innovation Park.



*It does not include transit time and waiting time.

Kansai Airport

Consolidated presence of major universities and research institutions

Osaka University

Overview of activities

It is one of the leading universities in Japan with 11 undergraduate faculties, 16 graduate schools, 6 affiliated research institutes, and 2 affiliated hospitals. It is famous as a university that is strong in biotechnology related studies, especially immunity research. It has produced many researches from the Graduate School of Medicine and the Graduate School of Biological Function who have made remarkable contribution to research in the biomedical field. In addition, it is actively working on the initiatives for commercializing

Main initiatives

At Osaka University, we proactively promote collaborative activities between industry, academia, and government, such as the establishment of "Joint Research Chairs" and "Research Alliance Laboratories," based around the Techno-Alliance Building of ou Suita Campus, as we strive for the construction of a platform that can continuously produce new research topics leading to innovation.

Notes (appeal points etc.)

- Realization of inter-organizational cooperation among industry and academia through Joint Research Chairs and Research Alliance Laboratories.
- In addition to joint and contracted research systems, establishment of the Professional Advisory Services Consultation system which provides advice regarding scientific problem solving. ·Promotion of technology transfer of intellectual property created
- from research. ·Construction of a regional ecosystem through the creation and support of venture businesses started at the university under the "Public-Private Innovation Program."

Inquiries

Address: 1-1 Yamadaoka, Suita-shi, Osaka 565-0871

TEL: +81-6-6877-5111

URL: http://www.osaka-u.ac.jp/en/index.html





Research Institute for Microbial Diseases, Osaka University (RIMD)

Overview of activities

Research Institute for Microbial Diseases (RIMD). Osaka University is the world's foremost institute for basic and clinical researches including microbiology, immunology, and oncology.

Main initiatives

Our mission is:

- -To explore the mechanisms of the pathogenesis of microbes and elucidate how our immune system works against those patho-
- -To understand our body system through genome analysis.

Overview of activities

Main initiatives

development of medicinal studies

- -To explore regulatory mechanisms in cancer cells and try to elucidate how cancer develops and progresses in our body.
- -To develop new therapeutic approaches to diseases including infectious diseases, hereditary diseases, and autoimmune

The Immunology Frontier Research Center (IFReC), an international hub for immunology research, was established in 2007 as part of the World Premier International Research Center (WPI)

Initiative program by the Ministry of Education, Culture, Sports

Science and Technology, Japan.By fusing immunology with

biological imaging and bioinformatics, we have strived to cultivate

new fields and conquer immune-related diseases. Reaching our 10th year in 2017, we are accelerating our expansion into medical

· Elucidation of molecular mechanism of innate immunity

·Elucidation of the pathogenesis of immune related diseases

·Functional elucidation of regulatory T cells and translation into

· Elucidation of mechanisms of parasite infection and development

· Elucidation of immune disease genes through bioinformatics

·Application of bioinformatics in the development of antibodies

Notes (appeal points etc.)

RIMD is certified as a "joint use/joint research location" by the Ministry of Education, Culture, Sports, Science and Technology, We maintain specialized facilities to study microbiology, immunology, and oncology, equipped with BSL2 and 3 laboratories in Animal Resource Center for Infectious Diseases and Central Laboratory for Biological Hazardous Microbes.

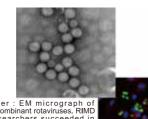
These research resources, facilities, and technologies are open to the research community and researchers are conducting collabora-tive projects with other research institutions and corporations.

Inquiries

Address: 3-1 Yamadaoka, Suita-shi, Osaka 565-0871

TEL: +81-6-6879-8264 (Administration) URL: http://www.biken.osaka-u.ac.jp/en/ Email: biken-info@biken.osaka-u.ac.jp





Over : EM micrograph of researchers succeeded i generating artificially

Right: The Toxoplasma

Osaka University Immunology Frontier Research Center (IFReC)

Notes (appeal points etc.)

A large number of foreign researchers work in IFReC and research environment and support system here meet the international

We are working on explaining immune phenomenon using an 11.7 T MRI, two-photon excitation microscope, etc., and prediction of immune reaction making full use of bioinformatics. In addition, as an initiative to collaborate with companies, we are building an open innovation laboratory and actively conducting joint research.

Inquiries

Immunology Frontier Research Center,

Osaka University

Address: 3-1 Yamadaoka, Suita-shi, Osaka 565-0871

TEL: +81-6-6879-4777

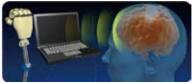
(Research Planning and Management Office) URL: http://www.ifrec.osaka-u.ac.jp/en/



Osaka University Hospital

Overview of activities

Osaka University Hospital is one of the leading advanced medical development hospitals in Japan, and its philosophy is to provide high-quality medical care and contribute to nurturing of healthcare professionals and development of medical treatment







Main initiatives

< Efforts toward accelerated development of innovative pharmaceuticals and implementation of special zone medical devices and pharmaceutical affairs strategy consultations as a clinical study core hospital. >

On August 7, 2015, Osaka University Hospital became the first hospital in the country to be approved by the Ministry of Health, Labour and Welfare as a clinical study core hospital under the Medical Care Act.Furthermore, from November 20 of the same year a "special zone medical devices and pharmaceutical affairs strategy consultations" was implemented targeting innovative medical device development projects in clinical study core hospitals within national strategic special zones, and on December 15, 2017 a further "accelerated development of innovative pharmaceuticals" was implemented targeting the development of pharmaceuticals.

Through these efforts we can expect to contribute to the expansion of Kansai's as well as Japan's medical industry

Inquiries

Address: 2-15 Yamadaoka, Suita, Osaka

565 -0871

TEL: +81-6-6879-5111

URL: http://www.hosp.med.osaka-u.ac.ip/english/

Institute for Protein Research, Osaka University (IPR)

Overview of activities

Institute for Protein Research, Osaka University was founded in 1958 with the mission of shedding light and explaining the principles of life activities through fundamental research on proteins. As a shared facility and collaborative research center for protein research, it promotes joint research through use of facilities and equipment with domestic and overseas protein researchers including the industry, and it is also working on developing young

Main initiatives

·Joint use of SPring-8 synchrotron and beamline, group of ultra-high magnetic field nuclear magnetic resonance (NMR) equipment group and cryo-electron microscope. Development and publication of protein data bank (PDB) as a member of the Worldwide Protein Data Bank (wwPDB)

·Promotion of multi-scale structural life science in the Division of Multiscale Integrative Protein Science which was established in

·Conducting numerous protein research laboratories seminars and international seminars

Notes (appeal points etc.)

A large number of shared equipment is available at Institute for Protein Research, Osaka University that even corporate researchers can use without any cost (some of the equipment are available for a fee).

It is designated as a shared collaborative research center of the country and it is equipped with the management system for conduct high quality research that meets the international standards

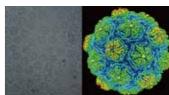
Inquiries

Address: 3-2 Yamadaoka, Suita-shi, Osaka 565-0871

TEL: 06-6877-5111

URL: http://www.protein.osaka-u.ac.ip/en/





Left : A protein of a huge Pf virus-like which weighs 7 million Da taken by the latest

Right: A solid structure with a resolution of 3.8 angstrom of the protein

Osaka City University

Overview of activities

Osaka City University fulfills the role of think tank for urban Osaka, and it aims to conduct educational research and contribute to the community in the field of "urban studies". Its goal is to promote the creation of new industries by consolidating the knowledge and wisdom of the university beyond the barriers of faculties, strengthening the brand power by creating new research and

Main initiatives

Consolidating the knowledge and wisdom of the university and

Development of next generation energy

Base of urban disaster management

Inquiries

URA Center

Address: 3-3-138 Sugimoto, Sumiyoshi-ku, Osaka-shi 558-8585

TEL: +81-6-6605-3550

URL: http://www.osaka-cu.ac.jp/en/research

Notes (appeal points etc.)

The Center for Health Science Innovation has established a system to create new products and services through industry-university collaboration with enterprises, with medical science of fatigue and anti-fatigue as the core. I accelerates cross-innovation in different industries and fields by leveraging the strengths of a university located in a large city, offering the possibility to make use of its system for innovative device development





Position of "health science" at Osaka City University

BioMedical Forum, Osaka Prefecture University

Overview of activities

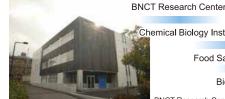
Osaka Prefecture University is an important member of the "Osaka Bio Strategy Promotion Council" established by Osaka Prefecture, and it has set up the Bio-Medical Forum for disseminating opinions and information on research strategy and initiatives for the bio industry.

Main initiatives

Bio-Medical Forum is comprised of three centers and two research laboratories, plans and proposes the strategy of biomedical research, and promotes good relationship between each member.



Live Cell Imaging Institute



hemical Biology Institute

Food Safety Science Research Cente

Biomedical Facility Center

College of Life, Environment, Members of and Advanced Sciences College of Engineering Veterinary Medical Center Kansai novation supportl nternational Education and Research strategy Center for Experimental research zone Animal Science Bio-Medical Facility Medical Device Analytical Center Center nanufacturers Pharmaceutical Radioisotope Research OPU-BMRC companies Pathological Evaluation Research for Food Pharmacological and Drug Discovery Antibody Therapeutics Toxicological Evaluation Research for Food Immunotherapy Regenerative Medicine Clinical Animal Medical Device Experiments

Bio-Medical Facility Center

Contact Us TEL: +81-7-2254-9128

Research Administration Center

URL: http://www.osakafu-u.ac.ip/english/

National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN)

Overview of activities

By working to promote joint research which contributes to the development of medical products, medical devices, etc. as well as medicinal plants and other living resources and research and development conducted by private companies, etc., we aim for the creation of a foundation to improve medical product and device technology while also engaging in investigation and research into the maintenance and improvement of people's health and investigation and research into people's nutrition and other dietary matters, thereby working to improve and increase public health and contribute to the improvement of national health preservation. With this as our goal, we are engaged with the 6 projects to the right as well as operations based on the Health

Main initiatives

- · Research and support of drug discovery related to fundamental
- · Research and support of drug discovery related to biological
- Promotion of development of drugs and other products
- · Surveys and studies pertaining to the maintenance and promo tion of the health of people
- · Surveys and studies regarding the nutrition and diet of people
- · Nutrition physiology tests of food

Inquiries

Address 7-6-8 Saito-Azaki, Ibaraki-shi, Osaka 567-0085

TEL: +81-7-2641-9811 (Main) URL: http://www.nibiohn.go.jp/en/





National Cerebral and Cardiovascular Center (NCVC)

Overview of activities

National Cerebral and Cardiovascular Center is a national center for advanced and specialized medical care and research. It promotes survey and research of cardiovascular disease and aims eradication of cardiovascular, setting its sights on advanced medicine. Our hospital is one of the world's leading centers conducting cooperative research in heart disease and cerebrovas cular disease which were caused by the same risk factors in one facility by specialists of each field. Research institute clarifies pathology and develops technology to fulfill the clinical members' needs. It enables problem solution more quickly that hospital and research institute work together. Moreover, research and development initiative center connects clinical field and research strongly.

Main initiatives

- ·Implementation of the greatest number of heart transplants in
- •Establishment of mobile telemedicine system
- ·A core facility of intravenous t-PA therapy and endovascular thrombectomy for acute stroke
- ·Basic research about pathogenesis and pathophysiology of cardiovascular diseases
- ·Development of artificial heart and blood vessels
- Cardiovascular surgery with less invasiveness ·Advanced check-up for cerebral and cardiovascular disease before onset

About moving

In July 2019, NCVC will move to the site of Suita marshalling yard "KENTO," directly connecting JR Kishibe Station.

In KENTO, new NCVC is aiming to form a large medical cluster. In addition, it is also aiming more contribution toward community medicine with Suita Municipal Hospital, that is opening in 2018 in the same KENTO ground.

New NCVC is focusing cardiovascular disease prevention, in addition to the forefront medical technique and research development with which NCVC has coped.

"Open Innovation Center (OIC)" will be set in new NCVC to advance the cooperation with companies and universities for the purpose to create whole new medicine and medical machines.





Inquiries

Address 5-7-1 Fujishirodai, Suita-shi, Osaka 565-8565

TEL: 06-6833-5012 (Main) URL: http://www.ncvc.go.jp/english/

RIKEN Center for Biosystems Dynamics Research (BDR)

Overview of activities

In BDR Osaka campus we develop the underlying technology for analysis and simulation of molecular dynamics inside living cells in order to comprehensively understand the systemic properties essential to living things such as resilience and robust homeostasis, leading to the development of better treatments and medi-

Inquiries

Business Partnerships Address: 6-2-3 Furuedai, Suita-shi, Osaka 565-0874.

F-mail: partner@ml riken ip URL: https://www.bdr.riken.jp/en/

Technological developments

- Various high-performance microscopes for live cell imaging
- ·High throughput imaging technologies combined with robotic mation and artificial intelligence
- Organ transparency technology
- ·Noninvasive sleep analysis technique based on respiration
- ·Creating model animals economically and efficiently by triple-tar geted CRISPR method
- •New fluorescent probes that enable various types of live cell imaging
- Special purpose supercomputer for drug discovery simulation
- •E-Cell, whole cell biochemistry simulation technology
- •Glass microfluidics lab-on-a-chip embedded with fine flow paths



AIST Kansai, National Institute of Advanced Industrial Science and Technology (AIST)

Overview of activities

AIST Kansai Center is working on developing diagnostic devices, drug discovery infrastructure technology, health and welfare equipment for "healthy society" centered on the biomedical

Notes (appeal points)

We are strengthening industry-academia collaboration through AIST Kansai informal gatherings.

We cooperate and collaborate with research institutions, government agencies, and companies including not only domestic but also international ones.



Main initiatives

- · Developing diagnostic devices such as ultrafast gene inspection
- · Bioproduction by genome editing and other technologies
- · Studies and search marker for brain disease

Inquiries

IIndustry-academia-government collaboration promotion office Address: 1-8-31 Midorigaoka, Ikeda-shi,

Osaka 563 -8577

TEL: +81-7-2751-968



Support Organization(Drug discovery etc.)

Japan Agency for Medical Research and Development (AMED) Department of Innovative Drug Discovery and Development

Overview of activities

By organizing Drug Discovery Support Network, we support biomedical R&D toward creation of novel drugs in cooperation with industrial and academic sectors. Moreover, we support development of innovative drugs and medication for orphan diseases through promotion of research activities regarding identifica-tion of drug targets and development of platform technologies for drug discovery as well as research for clinical application of medical technologies

Inquiries

Tel: +81-6-6372-1771 URL: http://www.amed.go.ip/en/



Pharmaceuticals and Medical Devices Agency (PMDA) Kansai Branch

Overview of activities

Focusing mainly on academia and venture companies for the creation of innovative drugs, medical devices regenerative medical products in Japan, we conduct regulatory science (RS) general consultations and RS strategic consultations (pre-consultation meeting) where we provide guidance and advice regarding planning the designs of studies and clinical trials which are required at the early stage of development. We can also provide advice regarding clinical trials and application materials in interviews utilizing the high-performance video conferencing systems connecting our Tokyo HQ and Kansai branch. Furthermore, we conduct investigations into whether the manufacturing facilities and manufacturing and quality controls of medical products, etc. comply with GMP/QMS/GCTP, etc.

Inquiries

URL: http://www.pmda.go.jp/ english/index.html TEL: +81-6-6374-6820

