

A New Age of Bio-Business

Toward the Creation of New Industry Clusters



Create the future

via bio-innovation

About JBA

History ■

JBA's roots date back to Shusei Kyokai (the Distilled Spirits Institute) established in 1942. Its name, after being changed to the Japanese Association of Industrial Fermentation, was renamed as Japan Bioindustry Association (JBA) in 1987.

Members ■

Corporate members: 214 companies
(pharmaceutical, food, chemical, cosmetic and machinery companies)

Public members: 103 organizations

Individual members: approx. 700
(university and corporate researchers)

Budget ■ 540 million yen (2015)

Board of Directors

Chairman

Sakayu Shimizu

Professor Emeritus,
Kyoto University

Professor,

Kyoto Gakuen University



President,

Representative Director

Osamu Nagayama

Chairman & CEO,

Chugai Pharmaceutical
Co., Ltd.



Executive Director

Yoshiaki Tsukamoto

Ex-Professor,

Tokyo Institute of Technology,
Ex-Director-General
of Shikoku Bureau of METI



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Mission

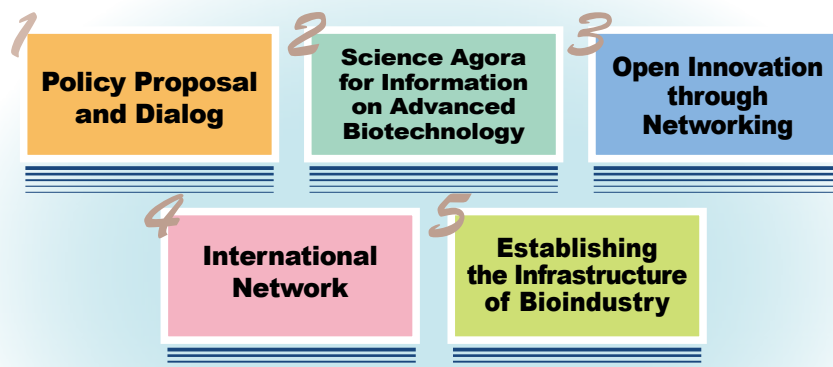
JBA contributes to bioindustry and related industries in the fields of health, environment and food

Our mission at JBA is to address the imminent problems facing mankind such as those concerning climate change and biodiversity and to facilitate implementation of appropriate measures as necessary, particularly by utilizing the latest developments in biosciences in an effective manner. To that goal, one of the most important priorities of JBA is to formulate and advance specific public policies through science-based reviews of regulations as well as to craft strategies to strengthen collaboration between industry, academia and government. Furthermore, to encourage the exchange of vital data and information, we realize that cooperation and communication with like-minded organizations throughout the world is of paramount importance. We are keenly aware of the value of providing free and open access to information regarding new technologies and products to all those who are interested in opportunities for innovation. On a more local level, our mission will also be expanded to help organize and develop regional associations for bioindustries in Japan. As an example of such endeavors, we hold an annual fair called BioJapan that comprises exhibitions, seminars for academia and industry, and business to business matching.

Three - year plan (2014 – 2017)

Attainment target

JBA will enhance the development base and platform functions of bioindustry, to contribute to the international competitiveness of the bioindustry in Japan.



5 Actions of JBA



New Study Groups Launched Out

Establishment of New Health Care Study Group

Social demands of human health

Having a background of a declining birthrate and an increase in lifestyle-related diseases, health care initiatives to address pre-disease conditions and to support health are increasingly important from the perspective of societal demands for quality of life (QOL) improvement and medical cost constraint.

With a large number of companies engaged in or oriented toward the health care business, JBA established this study group in fiscal 2014 to share information among members and respond to common issues.

Members of the study group enriched its lectures and discussion sessions, conducting short presentations on topics close to business and exchanging information. Mr. Takeo Niga and Dr. Susumu Kajiwara presented talks titled "Concerning Health Care Industry Policy" and "Overview of the Organization for Life Design and Engineering, Tokyo Institute of Technology," respectively. The study group also exhibited within the Open Innovation Zone at BioJapan 2014 and promoted business matching among companies.



Noboru Yumoto
Vice President
AIST



Takeo Niga
Senior Analyst
METI



Susumu Kajiwara
Professor
Tokyo Institute of Technology

Future Activities

JBA conducts lectures and information collection on specific health care topics including nursing care robots, "medical towns" that reorganize urban areas around hospitals, and medical treatment and nursing care services offered through collaboration between regions and universities. We are also exploring collaboration among JBA members in these fields.



Energizing the Research & Development Team on Functional Foods

Proactive proposals and communication regarding the new functional labeling system for foods

In order for the functional foods-related industry to prosper, JBA organized relevant issues, held discussions on resolution of the issues, and in 2013 launched a new research and development team aimed at proposing solutions to the government. In order to enhance information communication functions related to foods and health foods, we are undertaking actions centered on (1) proposal of solutions regarding functional labeling, regulations, etc.; (2) drafting of projects aimed at scientific evaluation of the 3 functions of foods, rational demonstration of safety, etc.; and (3) cooperation among business, academia, regional clusters, etc. for the development and overseas expansion of the functional foods-related industry (27 member companies and organizations).

■ Communication of Opinions and Proposals to Society

With an eye toward the content of guidelines released in March 2015 regarding the new functional labeling of foods, we focused on the sharing of issues and aggregation of opinions by conducting seminars on the functional food labeling system that started on April 1, 2015, along with workshops and idea exchanges among members, and further communicated opinions and proposals (see box below).

- Communication of opinions in response to public comments: "Food Labeling Standards Concerning the New Functional Labeling System for Foods (Draft)" (2014-09-26)
- Cooperation with Japan Association of Bioindustry Executives (JABEX) in submitting the proposal paper "Proposal for the Functional Labeling System for Foods: Aiming for the Extension of Citizens' Healthy Longevity and Industrial Revitalization" to the Cabinet Office Deputy Director-General, Cabinet Secretariat Health and Medicine Strategy Office, Ministry of Agriculture, Forestry and Fisheries, and Consumer Affairs Agency (Until Apr., 2015)

BioJapan

Exhibition in the Open Innovation Zone (Health Care Study Group, Research & Development Team on Functional Foods)

JBA took part in a joint exhibition (12 exhibits) in the Open Innovation Zone at BioJapan 2014, where Zone exhibitors and related bio-clusters conducted 44 presentations on the food and health care sectors and engaged in active business discussions. At BioJapan 2015 (2015-10-14~16), we will further expand the event to cover health care, functional foods, diagnostics, regenerative medicine, biochemicals, plant biotechnology, the environment, and more.

Recent Topics

Over several meetings of the study group, Mr. Takeshi Takeda discussed recent information on the new system and the necessity of an organization like the ODS (the U.S. NIH Office of Dietary Supplements), while Dr. Mari Maeda-Yamamoto spoke on the evidence-based development of processed products and functional agricultural, forestry, and fisheries products.



Keiko Abe
Professor Emeritus
The University of Tokyo



Takeshi Takeda
Managing Director
Global Nutrition Group, Inc.



Mari Maeda Yamamoto
Director of Food Function
Division Natl. Food Research
Institute, NARO

Future Activities

With specific products coming to market under the new functional labeling system, the study group will debate and issue opinions on issues and problems with the new system, including policy matters. It will also engage in consideration of topics including rational methods (i.e. standards) for verifying safety, assurance of first-mover benefits, and functional label patent claims. The study group will also cooperate closely with the "Development of Next-Generation Agriculture, Forestry, and Fisheries Products and Foods" strategic innovation program (SIP), which seeks to create technology in the industry and for which Ms. Abe serves as Sub-Program Director, and will further ramp up activity aimed at the prosperity of the functional foods-related industry.

Launch of the Plant Biotechnology Study Group

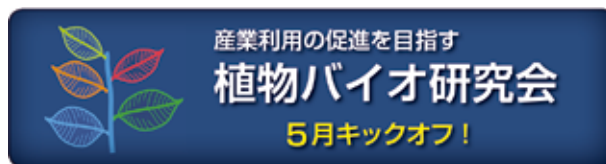
Reassessing the potential of plants and promoting industrial usage

JBA has established a new study group with the aim of conducting discussions across departments and specialties, selecting basic and mediating technologies that should be developed, and engaging in collaboration among industry, government, and academia to break through problems. The group welcomes participation.

Special members, sponsoring members, general members, venture members, public members, and representatives of academia (including independent administrative institutions) are all invited to inquire.



Daisuke Shibata
Department Director, Kazusa DNA
Research Institute



Activities about the Nagoya Protocol

At the 10th meeting of the Conference of the Parties to the Convention on Biological Diversity (COP10) held in Nagoya in October 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (hereinafter, the Nagoya Protocol) was adopted. This is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. Although the Nagoya Protocol was adopted as a result of difficult international negotiations for many years, there are a number of ambiguous points in its major provisions with regard to their interpretation. While the Nagoya Protocol entered into force in October 2014, the government of Japan has been discussing the formulation of Japan's domestic measures for the ratification of the Nagoya Protocol and its implementation in Japan.

Under these circumstances, JBA, Japan Association of Bioindustries Executives (JABEX) and four other industry groups submitted an opinion paper on the Nagoya Protocol to the Ministry of Foreign Affairs, the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment in October 2014. The opinion paper notes that, while the protocol bears the name of the Japanese city Nagoya, the government should not act too hastily but must carefully consider every issue in the Protocol through dialogues with the bioindustry sectors.

Future Activities

JBA will continue its activities to ensure that the implementation of the Nagoya Protocol facilitates the utilization of genetic resources in a fair and equitable way and contributes to the conservation of biological diversity and the sustainable use of its components.



The Nagoya Protocol published by CBD Secretariat (left) and its Japanese translation by JBA (right)

Launch of the Bio-Business Seminar

JBA has assumed the Pharmaceutical and Other Companies Top Management Seminar that had been conducted as an activity of the Metropolitan Bio Network Japan until fiscal 2013. In 2014, we launched the Bio-Business Seminar as a venue at which executives and key persons from member companies can present information on research and development, business strategy, core technologies, case studies of external resource usage, and other topics, sharing this information with JBA members.

■ Seminar Content (8 sessions)

Session 1: "FUJIFILM's New Business Challenge" (2014-02-06)

Session 2: "Mitsubishi Chemical Holdings' Health Care and Green Agribusiness Strategy" (2014-02-24)

Session 3: "TORAY's Advanced Film Technology Creation and Innovation Strategy" (2014-05-20)

Session 4: "TEIJIN's Technological Innovation and Green Chemistry & Health Care Business Strategy" (2014-08-07)

Session 5: "Daiichi Sankyo's Biologics Strategy" (2014-09-16)

Session 6: "Ajinomoto's R&D: Focusing on the World of Amino Acids" (2014-11-19)

Session 7: "Kao Corporation's Daily Goods Bio

Strategy: Sustainable, Seniors, and Global" (2014-12-26)

Session 8: "Sumitomo Chemicals' Life Sciences Business: Toward the Rollout of Business on the Themes of Foodstuffs, Health, and the Environment" (2015-01-19)

Future Activities

In fiscal 2015, too, we will make the seminars an opportunity for open innovation that crosses industries and sectors, and a valuable venue for more member companies.



Seminar by
Yasuhiro Yoshioka,
FUJIFILM Corporation

Launch of International Partnership Seminars

In 2014, JBA launched the International Partnership Seminar for foreign embassies, regional and state government organizations, and overseas biotechnology organizations. The seminar is a venue to communicate the latest bio-related topics and selected information from overseas, and to provide up-to-date information to corporate members and opportunities for interaction among members.

■ Seminar Content (6 sessions)

Session 1: "From San Diego: Mobile Health and the Recent Widening of the Bio Industry" (2014-04-14)

Session 2: "The Current State of Life Sciences in Medicon Valley" (2014-06-30)

Session 3: "Europe's Advance into the Life Sciences Sector: Why Scotland is an Option – Tips and Points for Making Use of Scotland –" (2014-07-14)

Session 4: "Life Sciences in Canada" (2015-02-09)

Session 5: "Overview of the Pharmaceutical and Bio Industries of Catalonia, Spain" (2015-02-23)

Session 6: "Overview of Biomass Research Led by Queensland University



Stephen Dibert
Global Practice Lead Foreign
Affairs, Trade and Development
Canada

of Technology (Australia) and the Potential for International Industry-Academia Partnerships" (2015-03-27)

Future Activities

JBA has 31 embassies and regional and state offices in Japan as public members. We will continue to plan and offer seminars in partnership with these members.



Queensland state seminar

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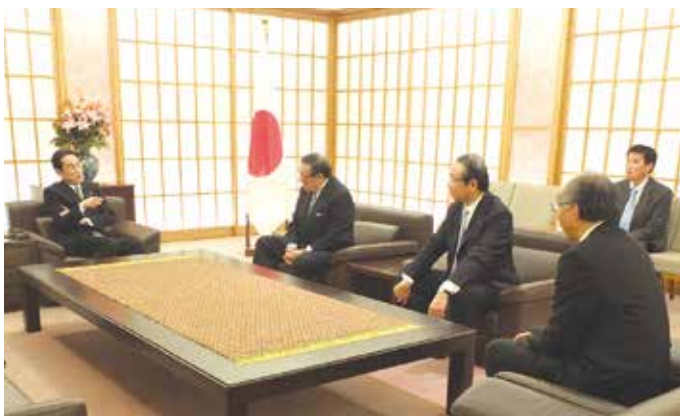
Policy Proposal and Dialog

JBA carries out policy proposals and dialogs with government bodies on biotechnology and industrial issues in cooperation with member companies, universities.

In cooperation with the Japan Association of Bioindustry Executives (JABEX; Chairman Kouichirou Aramaki), JBA has been offering a variety of policy proposals and retains opportunities for dialog for the sound development of biotechnology and bioindustry.

Policy Proposal

JBA visited LDP Executive Acting Secretary-General Hiroyuki Hosoda (Chairman of the Diet Members' Promotion Alliance for Life Sciences), Minister for Foreign Affairs Fumio Kishida (Secretary-General of the aforementioned Alliance), and Minister of the Environment Yoshio Mochizuki to present the industrial position on the Nagoya Protocol. We made suggestions to the Cabinet Secretariat, the Cabinet Office, and other relevant parties concerning the 5th Term of the Science and Technology Basic Plan, bio-ventures, functional foods labeling, and other topics.



Minister for Foreign Affairs Kishida (left)



LDP Executive Acting Secretary-General Hosoda (left) and Representative Aramaki (right)



Minister of the Environment Mochizuki (second from right)

Policy Dialog

An opinion on "Human derived biological sample usage promotion for drug discovery" was suggested at "Council for Genomic Medicine Promotion" of the Cabinet Secretariat Health and Medicine Strategy Office by our steering committee member Dr. Toshinori Agatsuma.

Expression of Qualified Opinions

JBA expressed opinions on National Strategic Economic Growth Areas, food labeling standards, the new functional labeling system for foods, and other topics. We supported the members' activities on so called the System to Removing Gray Zone Areas and the System of Special Arrangements for Corporate Field Tests.

Government policy seminars

JBA holds ongoing policy information seminars with presentations by ministry and agency officials in charge of drafting and promoting policy measures.

- "Overview of the Center of Innovation S&T Radical Innovation and Entrepreneurship Program (COI STREAM)" (Ministry of Education, Culture, Sports, Science and Technology) (2014-06-11)
- "Overview of Policy Measures Concerning the Genetic Testing

Business" (Ministry of Economy, Trade and Industry) (2014-06-12)

■ "Overview of 2014 General Strategy for Science and Technology Innovation" (Cabinet Office) (2014-09-02)

■ "Overview of the Leading Package Strategy: Toward the Realization of Innovative Pharmaceuticals, etc. Ahead of the World" (Ministry of Health, Labour and Welfare) (2014-09-26)

■ "Toward the Strengthening of Social Security Policy and the Development of the Pharmaceutical Industry" (Ministry of Economy, Trade and Industry) (2015-01-09)

■ "Overview of Overseas Pharmaceutical Market Trends: Current State and Issues as Seen from the Relationship with Policy Measures" (Ministry of Health, Labour and Welfare) (2015-03-12)



Government policy seminar

2

Science Agora for the Information on Frontier Biotechnology

JBA provides recent issues on biotechnology and new technical information for the industry, along with the discovery of seeds and industrialization, in cooperation with member companies, universities, and government bodies.

JBA gathers information on advanced biotechnology in Japan and overseas, conducts surveys on the latest development trends, discovers technological seeds that will lead to new industries, shares information with members and communicates information externally through lectures and seminars. Furthermore, JBA proposes project concepts that should be conducted in cooperation with industry, government, and academia.

Expanding Lectures and Seminars

In fiscal 2014, JBA hosted a total of 71 workshops, seminars, lectures, symposiums, and study tours drawing 5,737 participants. Along with lectures and seminars on drugs, medical care, the environment and manufacturing, and the health care sector, JBA took up the topic of the plant biotechnology sector. In addition to targeting niche and compound domains, this combines biotechnology with basic technology that supports cutting-edge science, and will lead to the creation of new businesses. JBA's lecture covered technological information from overseas, and plans that propose solutions for new industrial technologies.

Key words from advanced information seminars

regenerative medicine, quality control for cultured cells, 3D printers, organ regeneration, culture mediums, sugar chain drug discovery, PAT and RTR, bone immunology, medical tourism, medical care in the Middle East, myocardial regeneration therapy, peptide drug discovery, omics analysis, space drug discovery, medical devices, reactive supramolecular hydrogels, single-use, PET-related technology, drug repositioning, biological three-dimensional tissue construction

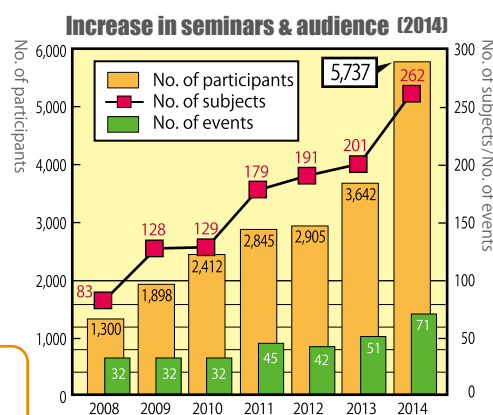
synthetic biology, artificial cell models, isolation of and search for microorganism strains, compound microbial systems, biomass utilization, algae, metabolic pathway design, bottom-up genome design, evolution experiments, green phenol, photonics polymers, herbaceous raw materials, bio-refineries, industrial lipase, Antarctic-grown yeast, bio-surfactants, silicon biotechnology

functional food labeling system, functional crops, "zero" drinks, histamine control, stress reduction effects, anti-obesity food ingredients, taste and function, food secondary function analysis, drink-refreshment sensors, sarcopenic obesity, DNA chips

bio interfaces, plasma, mathematical models and network analysis, brain science, optical topography, psychometrics, visualization of the heart

pre-disease stage management, robot suits, needle-free syringes, bio-devices, cell chip, healthy society, blood biomarkers for depression, personal smart health care, wearable biometric information sensor modules, biological interfaces

Green biotechnology, carbon dioxide fixation farms, woody biomass, parasitic weed control technology, micro-tuber production technology



Advanced Themes and Leading Lecturers

Drawing on the results of questionnaires aimed at members, we selected themes appropriate to JBA lectures. We also proactively held seminars that are planned and proposed by corporate members, taking up themes that included brain science, space drug discovery, and plasma, with the aim of fusing different sectors and industries and creating new businesses.

Expanding Potential for New Business at Networking Events

With the formation of networks among participants a key objective, JBA strives holds seminars with the goal that these will lead to the creation of businesses and markets, proposals for policy,

and business matching. Networking meetings and business card exchanges have taken root as activities following our lectures, with participants forming long lines to meet speakers every time.

Enhancement of member privileges

After the conclusion of events, JBA promptly posted reports on its website and made presentation slides available as PDF documents, limited to JBA members. JBA also enhanced its video streaming service for corporate members, with a total of 36 seminars and 85 presentations available. In total, viewing requests have come from 182 persons, for 461 seminar videos and 1,110 presentation videos. (fiscal 2014)

JBA is enhancing its seminars for corporate members in order to deliver fresh information. Seminars proposed by corporate members have also taken root at JBA.

Seminar speaker



"New Development in Surgery:
Cardiac Regeneration Service"
Yoshiaki Sawa
Professor, Osaka University



"Science and Technology Policy
in Japan and Innovation Strategy
in the Chemical Industry"
Kazuhito Hashimoto
Professor, The University of Tokyo



"Development of a Special
Peptide Drug Discovery Platform
and its Future Outlook"
Hiroaki Suga
Professor, The University of Tokyo



"The Potential for Culturing
Technology Standardization and
Quality Control Technology Using
Images of Cultured Cells
in Regenerative Medicine"
Ryuji Kato
Associate Professor, Nagoya University



"Application of Textile Materials
to Biological Interfaces and the
Future Outlook: Wearing Functional
Material 'hitoe' Enables Continuous
Measurement of Biological
Information"
Keiji Takeda
Manager, Toray Industries, Inc.



"Principles of Optical Topography
and Examples of Application in
Brain Science"
Atsushi Maki
Chief Researcher, Hitachi, Ltd.



"Substance Production/
Environmental Issues and
Network Analysis: Assumptions
for Biodiesel Production Routes"
Sachiyo Aburatani
Leader, AIST



"PROESA™: breakthrough
technology for production of
advanced biofuel from cellulosic
biomass"
Mr. Pierluigi Picciotti
Business Development Director,
Beta Renewables S.p.A.

Hosting of comprehensive Symposium on Biopharmaceutical Manufacturing

JBA's Bioengineering Study Group hosted a comprehensive symposium titled "New Developments in Biopharmaceutical Manufacturing." The event discussed possibilities and issues related to manufacturing

process monitoring and the real-time shipping of biopharmaceuticals, and further deepened understanding with an exhibition of manufacturing equipment.

Hosting of Local Study Tours

JBA held study tours of locations including the Shizuoka Cancer Center and the Asahi Breweries Kanagawa Brewery, collecting on-site information during each tour.

Rotating gantry irradiation
chamber for proton beam
therapy (Shizuoka Cancer
Center Pharma Valley
Project site visit)



2,000 L single-use culture tank
(Nippon Zenyaku Kogyo
(ZENOAQ))



The Asahi Breweries Kanagawa Brewery study
tour heard a lecture on "Contributions to the
Construction of a Low-Carbon Society," observed
the beer brewing process and environmental
conservation initiatives, and engaged in networking.

Cooperation and Strengthening of Activities in the Green Sector

In three green biotechnology-related study groups (the study group on fermentation and metabolism, the study group on alcohol fermentation & biomass utilization, and the study group on new resource bioconversion), JBA deepened cooperation aimed at strengthening structures and initiatives in the sector. In fiscal 2014, we planned seminars, lectures at BioJapan, and study tours that addressed the shared theme of algae. On December 12, JBA held a joint symposium by the three study groups, titled "The Future of Growth Strategies in Green Businesses with Algae." Perspectives of elements spanning biomass raw materials to conversion, commercialization,

and raw materials recycling, we are creating scenarios for green biotechnology regeneration that leverage the strengths of each study group, and are undertaking activities with a view toward making proposals for national projects.



Fermentation and
Metabolism Study Group
Jun Ogawa
Group Leader,
Kyoto University



Alcohol Fermentation and
Biomass Utilization Study Group
Masahiro Samejima
Group Leader,
The University of Tokyo



New Resources
Bioconversion Study Group
Masaharu Ishii
Group Leader,
The University of Tokyo



Moderator
Shigeru Okada
Associate Professor,
The University of Tokyo

Research & development project

To strengthen the development base and platform functions of bioindustry and improve the international competitiveness of Japan's bioindustry, JBA is currently undertaking four entrusted research and development projects.

■ Biomass Energy Technology Development and the Project for Research and Development of Valuable Technology for Biofuel Manufacturing: NEDO FY 2013-2016

JBA is engaged in research and development projects on the following two themes adopted within the Project for Research and Development of Useful Elements for Biofuel Manufacturing, technological development of which is expected to reach commercial-scale practical application in 2020.

(1) Manufacture of Innovative Saccharification Enzyme Industrial Production Microorganisms and Development of Production Technology for Saccharification Enzymes for the Creation of Bio-Fuel Business

This project is conducting studies to strengthen the activation of component enzymes and overcome the decline in the saccharification rate, in order to enhance the functionality of saccharification enzymes. With regard to optimal saccharification enzyme composition, the project has identified correlations among various substrate biomasses. The project also studied various production criteria using a mini jar fermenter, calculated the manufacturing cost and the scale and construction costs for manufacturing facilities, and conducted analyses from economic angles, with the aim of developing low-cost mass production technology for saccharifying enzymes.

(2) Fermentation Production Technology Using Beneficial Microorganisms

This project studied 1) development of microorganisms for simultaneous fermentation of C5/C6 sugars, 2) development of a simultaneous saccharification and parallel multiple fermentation process, and 3) process design packages, in order to achieve an ethanol production concentration of 5%w/v or higher and an ethanol fermentation yield of 95% or higher at a pilot scale of several m3 or higher. The project also established standard evaluation systems for enzyme volume, inocula volume, ventilation level, etc. for the creation of standard substrate samples and for yeast efficiency, and selected optimal bred strains.

■ Development of Highly Functional Genome Design Technology for the Realization of Innovative Biomaterials: Survey of Innovative Biomaterial Marketability and Global Trends in Competing Technologies

Ministry of Economy, Trade and Industry (FY2013-2016) Highly Functional Gene Design Technology Research Association (contracted project)

In addition to ongoing surveys of synthetic biology research and innovative biomaterials, this project conducted a detailed survey of the U.S. Department of Defense's Living Foundries: 1000 Molecules Program, with the aim of creating breakthrough biomaterial manufacturing technology. The project also led a survey of marketability of analytical equipment born from the aforementioned Project's long-chain DNA synthesis technology.

Destinations for overseas survey visits

- (1) U.S. Synthetic biology research facilities: Zymergen, Inc., Joint BioEnergy Institute (JBEI), J. Craig Venter Institute (JCVI), Synthetic Genomics Inc.(SGI), Broad Institute of MIT and Harvard, Harvard University, Illinois University
- (2) 11th Annual World Congress on Biotechnology/Philadelphia
- (3) International Conference on Natural Products /SanDiego

■ Development of Cell Manufacturing and Processing System for the Industrialization of Regenerative Medicine, for Regenerative Medicine Products Derived from Human

Pluripotent Stem Cells (Cardiac, Nerve, Retinal Pigment Epithelium, Liver Cells) and for Regenerative Medicine Products Derived from Human Mesenchymal Stem Cells NEDO (FY 2014-2018)/Stem Cell Evaluation Technology Research Association (allotted research)

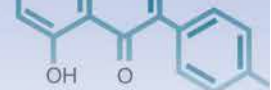
This project conducted limited SWOT analysis and cross-SWOT analysis of equipment and basic technologies for regenerative medicine product manufacturing systems. Further, in combination with cross-SWOT analysis based on the Ministry of Economy, Trade and Industry's SWOT analysis of industrialization trends in Japan and the current state of industries surrounding regenerative medicine, it determined strategic options (business opportunities) for new acquisition of regenerative medicine business markets. In addition, the project conducted a survey of recent trends in Japan and overseas involving the foundations for clinical application, the practical realization, and the industrialization of regenerative medicine and human stem cell technologies, and formulated an outline of a global market acquisition strategy for a regenerative medicine product manufacturing system. The project also proposed the catch phrase "KotoDukuri (Industrialization)" for regenerative medicine.

■ "Development of Basic Technology for the Creation of Next-Generation Pharmaceuticals for Individualized Medicine (Technology for the Manufacture of Next-Generation Therapeutic Antibodies Meeting International Standards)" Project: Survey of Trends Concerning Next-Generation Biopharmaceutical Production Technologies and Intellectual Property

METI (FY 2013-2017)/Manufacturing Technology Association of Biologics (MAB) (allotted research)

Europe and the U.S. have taken a significant lead in biopharmaceutical manufacturing technology. JBA surveyed intellectual property that likely to become an obstacle in the development of manufacturing technology in this project, and continued analysis of threats in the area, such as the impacts of prior intellectual property. In existing biopharmaceutical manufacturing lines, the normalization and standardization of manufacturing lines through single-use technology is moving forward, and there are fears that the multiple guidelines and regulations that have been established may become obstacles. This project is collecting information on leading actions in Japan and overseas through intellectual property and academic information, corporate data available on the Internet, information from academic papers, and other sources, and is undertaking surveys for the purpose of providing information to strategic initiatives under this project in the future. In terms of intellectual property, the project has analyzed and summarized materials surveyed and collected from the previous fiscal year. It has also carried out organization of information focused on genetic modification technology aimed at genetic modification to improve conditions for cell culture, vectors, high expression of proteins, and productive cell screening systems, and has further performed analysis of production and culturing methods. It collected information centered on academic papers, and sorted findings into information related to antibodies overall, the drug efficacy of new structurally modified antibodies, side effect mechanisms, antibody screening, and genome editing.

The project took part in international academic meetings and exhibitions rich in information related to antibodies, collected up-to-date information, and summarized the information with the chief purpose of manufacturing methods and technological development concerning cells, culturing methods, purification techniques, single-use, and more.



3

JBA Action

Open Innovation through Networking

JBA provides opportunities to help the development of biotechnology and industry.

JBA holds the partnering bio event BioJapan as an effective mean for creation of opportunities, promotion of alliances, and construction of business platforms. Moreover, functioning as a hub of All Japanese Bio Regions Committee, JBA aims to form networks among bio-related parties, and support development of bio-ventures through mutual cooperation.

BioJapan

A variety of companies and academic institutes focused on biotechnology participate in BioJapan to make open innovation a reality.



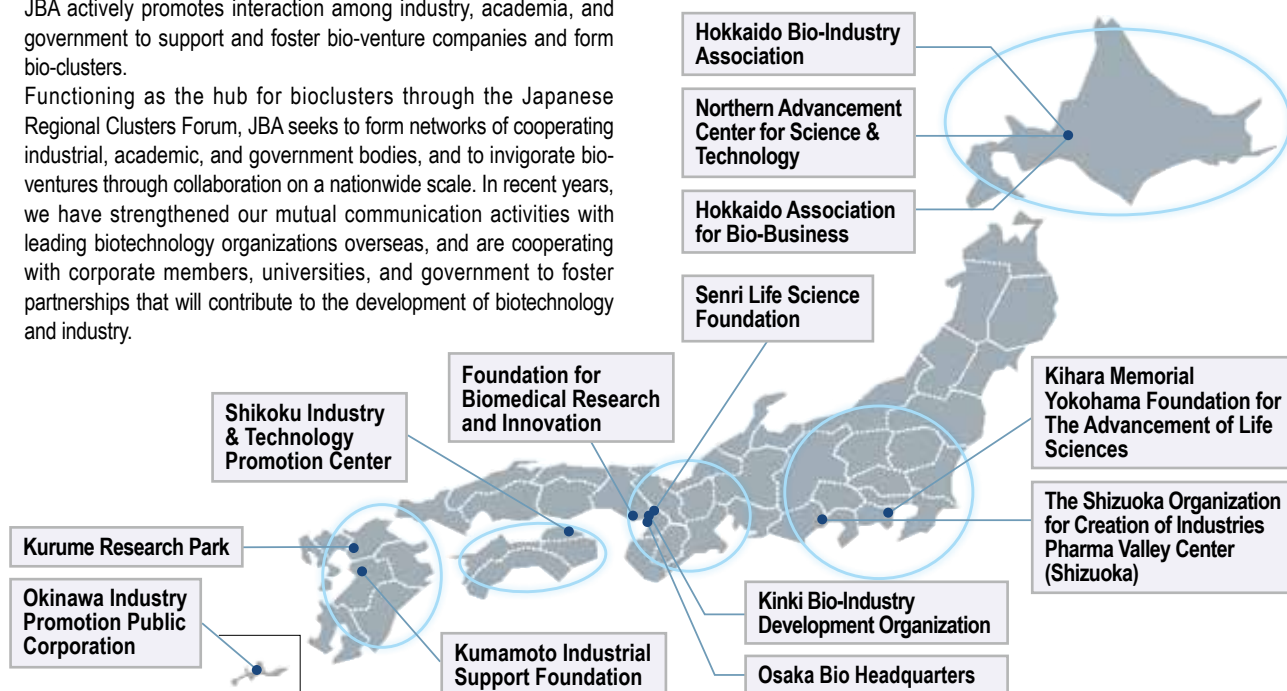
Opportunities for creating open innovation

- Collaborative research ● Licensing in and out of the technology
- Business collaboration ● Business Partnerships
- Creating innovation in fusional areas

Support for bio-venture companies and bio-clusters

Through networking with nationwide bio groups and clusters, JBA actively promotes interaction among industry, academia, and government to support and foster bio-venture companies and form bio-clusters.

Functioning as the hub for bioclusters through the Japanese Regional Clusters Forum, JBA seeks to form networks of cooperating industrial, academic, and government bodies, and to invigorate bio-ventures through collaboration on a nationwide scale. In recent years, we have strengthened our mutual communication activities with leading biotechnology organizations overseas, and are cooperating with corporate members, universities, and government to foster partnerships that will contribute to the development of biotechnology and industry.



All Japanese Bio Regions Committee

All Japanese Bio Regions Committee has constructed a system by which major regional industrial, academic, and government bio organizations can strengthen networking, share information, consider future policy, and cooperate mutually.

Biocluster Summit: Strengthening International Partnerships

in BioJapan 2014

Biotechnology organizations from Japan, Thailand, New Zealand, the U.S., France, Germany, Scotland, and Spain came together to deepen discussions on the current state of human resource development and case studies of cluster policy that leads to business creation.

Committee Meeting: Partnerships in Japan and Overseas

(2015-01-14)

JBA engages in exchanges of ideas with other parties on many topics, including issues faced by regions and future solutions, the current state of industrial, academic, and government partnerships, the state of partnerships and cooperative activities with overseas clusters, and proposals to the national government.

Support for the Formation of Bio-venture Alliances

JBA engages in activities to support the formation of bio-venture alliances. At BioJapan 2014 we operated the JBA BIOTECH SQUARE pavilion for bio-ventures, where we supported partnering activities. The coordinators of the pavilion stepped into business development on behalf of the bio-ventures by working to promote business matching with major medium-sized enterprises.

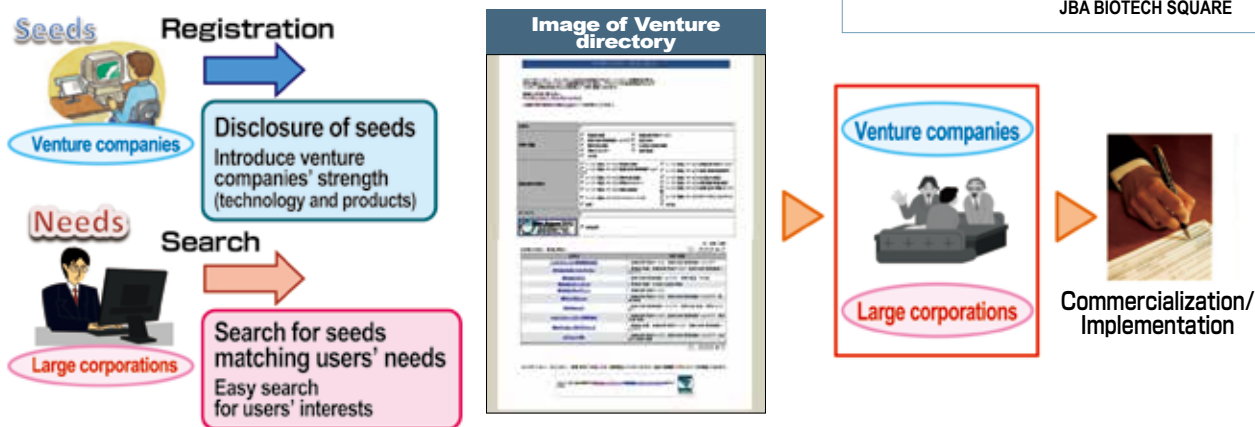
Preparation of a Bio-venture Directory

In conjunction with open innovation, JBA is collaborating with bio organizations nationwide to aggregate and release basic information online concerning the nation's increasingly-watched bio-ventures, with the aim of accelerating alliances among clusters and companies in Japan and overseas.



JBA BIOTECH SQUARE

Implementation of Open Innovation by using Bio-venture Directory



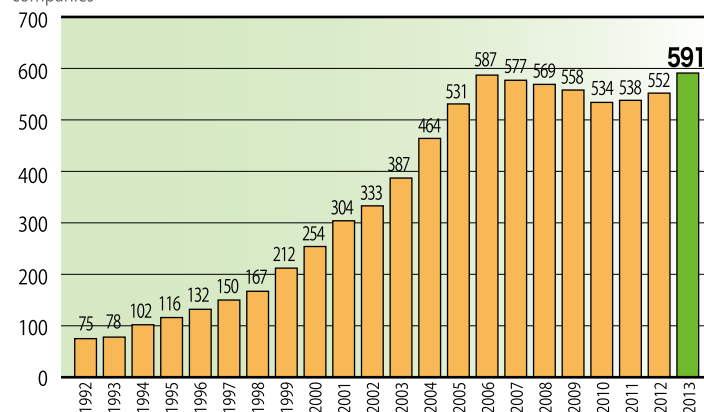
(Please click "Bio Venture Directory" at the JBA website)

Preparation of statistical data on bio-venture business

In fiscal 2014, JBA conducted a questionnaire survey of bio-ventures across Japan and statistical analysis. In addition to statistical surveys, we conducted an ongoing original survey of topics including trends in joint research and licensing agreements between bio-ventures and large and medium-sized companies. The results were gathered in the 2014 Survey of Bioventure Statistics and Trends (with an overview available on the JBA website). Our look at the trends surrounding bio-ventures, joint research, licenses, and agreements between bio-ventures and medium-sized companies reveals that these remain stable, with an upward trend in results such as acceptance of milestones. A portion of the survey ("New Public Offerings and Fundraising by Bio Startups") was posted on the website of the Hitotsubashi University Institute of Innovation Research as a result of the joint research.

Number of companies

Number of bio-venture companies



2014 Survey of Bioventure Statistics and Trends (JBA)



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JBA Action

International Network

JBA provides international information on biotechnology and bioindustry in cooperation with member companies, universities, and the government.

As one of our international activities, JBA offers overseas biotechnology information and related events to members, and also provides information on Japan's biotechnology industry and opinions on international issues to parties overseas, speaking as the Japanese biotechnology organization.

We also cooperate with overseas biotechnology groups to promote interaction with JBA members through their participation in BioJapan. Reflecting the situations of member companies, JBA builds networks which are difficult to achieve as an individual or a single company.

Overseas bio-organizations having agreements with JBA

★ ... JBA members (31 organizations as of April 2015)

★ ... Overseas biotechnology organizations with which JBA has written agreements (as of April 2015)



JBA events and activities for open innovation in 2014

- Participation in BIO International Convention 2014 (San Diego, June)
- Participation in Japan-Taiwan Biotechnology business meeting/ BioTaiwan2014, Cooperation with interchange association (Taiwan, July)
- Participation in BIOPharm America 2014 (Boston, September)
- Participation in BIO-Europe2014 (Frankfurt, November)
- Participation in BIOTECH SHOWCASE 2015 (San Francisco, January)
- Participation in Biocom's Global Life Science Partnering Conference (San Diego, February)
- Participation in BIO-Europe Spring2015 (Paris, March)
- Participation in BIOAsia2015 (Tokyo, March)



Meeting with overseas cluster (BioJapan 2014)



Exchange of MOU with BIOCOM (BIO SanDiego 2014)

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JBA is addressing the improvement of infrastructure for biotechnology and industrial development in cooperation with member companies, universities and government.

In the bioindustry field of food and environment, JBA gathers and shares information on relevant laws and regulation in enactment process and practical application to member organization and submit opinion as the industry. At the same time, JBA coordinates improvement of bioindustry infrastructure by participating in national research projects, fostering training of young scientists as well as awarding prizes.

Explanatory meeting on the utilization of the Cartagena Act

Cartagena Act's overall picture and application process were explained by Ministry of Education, Culture, Sports, Science and Technology (MEXT), Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI) and National Institute of Technology and Evaluation (NITE) concerning simplifying and expediting the application process for the conduct of wide range R&D and industrialization. Following the explanatory sessions, individual consultations were arranged. (Tokyo 2015-01-21, Osaka 2015-01-27)

JBA summarizes the requests of our members and engages in opinion exchanges and negotiations with supervising government bodies on simplified approval applications and other operational improvements of the Cartagena Act. These activities resulted in revisions to the Minister of Economy, Trade and Industry manual for application for ministerial approval ([2014-09-26](#)), in significant revisions to the Ministry of Health, Labour and Welfare GILSP list, and in other relevant documents.

JBA attended COP-MOP7 (7th meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety), held in PyeongChang, South Korea in October 2014, and attended COP12 (12th meeting of the Conference of the Parties to the Convention on Biological Diversity) as a scientific expert working with the Japanese government. JBA engaged in discussions on guideline revisions for genetically modified organisms at COP-MOP7, and provided expert knowledge-based counsel on a new candidate agenda item, synthetic biology.

Publication of “Future Society Pioneered through the Contributions of Biotechnology”

As a tool for communicating a future society visions built on biotechnology (technology, lifestyles, and industrial development trends), JBA is running a 10-part series by leading experts in their respective fields in the magazine *B&I*.

“Recent Advances in and Future Prospects for Plant Breed Improvement Technology” Ezura Hiroshi (Professor University of Tsukuba)

“Toward a ‘Healthy & Happy’ Society: A Picture of Industry, Technology, and Services” Noboru Yumoto (Vice President AIST), Toshihiko Ooie (Deputy Director AIST)

Explanatory meeting on the utilization of the Cartagena Act (Tokyo)



COP-MOP7 (Pyeongchang, Korea)



**“Future Society Pioneered
through the Contributions of Bio”**

Provision of Technical Information on Key Interest to Industry

The new technological domains of NBT (new breeding techniques) and synthetic biology call for ongoing scrutiny in terms of both technological development trends and regulatory trends, as areas that will have major impacts on not only basic research but also commercial production. JBA provides up-to-date and accurate information through seminars and other means, for the members to make use of these technologies and respond aptly to regulations.

“Overview of New Breeding Techniques (NBT) and the State of Research and Development” (2014-08-29)

Yutaka Tabei (Senior Principal Researcher, National Institute of Agrobiological Sciences (NIAS))

This presentation discussed the potential for NBT which has attracted attention as a fast, efficient breeding technique that does not leave traces of genetic manipulation in successive generations along with related safety and necessary regulatory issues.

Synthetic Biology Seminar: “Recent Scientific and Technological Trends and Issues Surrounding Synthetic Biology” (2015-03-05)

Daisuke Kiga (Associate Professor, Tokyo Institute of Technology)

Kenji Tsuge (Project Assistant Professor, Keio University)

Masashi Tachikawa (Professor, Ibaraki University)

Among the recent fast moving areas of synthetic biology trend, artificial genetic circuits and synthetic metabolic engineering were talked by two of the experts in Japan. Also the regulatory aspect from the view of socioeconomic view point was introduced.



Yutaka Tabei

Seminar



Daisuke Kiga



Kenji Tsuge



Masashi Tachikawa

Intellectual property

Securing intellectual property issues on venture companies as well as on functional food ingredients were discussed by the working groups and issues were identified by face to face hearing and by questionnaires. Also we have submitted position papers in two separate occasions on “natural principle” which a guidance document was given from U.S. Supreme Court ruling by US Patent and Trademark Office.

Industry-academia communication and collaboration

Fostered Training for Young Company Employees: JBA Bio-Leaders Course 2014

JBA held a training course for 30 trainees (23 men, 7 women; average age 31) on September 2-4, 2014, at the Makuhari Seminar House in Chiba Prefecture. Through group work, the trainees experienced the creation of business plans based on technological seeds drawn from four themes and six patent applications provided by the Japan Science and Technology Agency. A diverse range of trainees from 21 companies to the program benefitted from this opportunity of inter-industry communication.

Conducted Training for Graduate Students: Short-term Internships at BioJapan

Taking advantage of the opportunity offered by BioJapan as an event that gathers much of the biotechnology industry, JBA also offered short-term internships to graduate students to learn about the biotechnology industry and better envision of future working in the industry. In addition to involvement in lectures and debates, practical training to let the students take part in seminar operation and involved in business matching events, provided exposure to business settings.



Group work



Discussion

Access to Genetic Resources and Benefit-sharing

Awareness Raising Activities on Access to Genetic Resources and Benefit-Sharing (ABS)

JBA has continuously contributed to enhance public awareness and understanding of access to genetic resources and benefit-sharing (ABS). We organize public seminars in major cities nationwide to provide users of genetic resources with up-to-date information on ABS. We also conduct individual on-site seminars in response to requests from companies, universities and research institutes. As a tool for awareness raising activities, we translated the Nagoya Protocol into Japanese and developed the Guidelines on Access to Genetic Resources for Users.

Help Desk on ABS

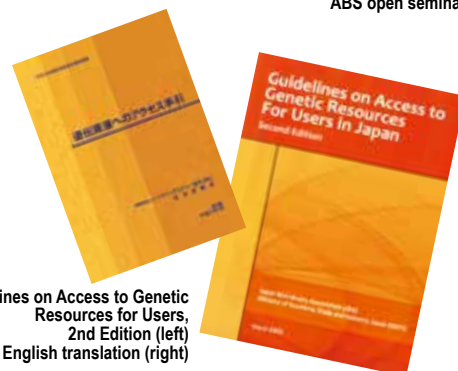
JBA has established Help Desk, i.e. consultation service concerning ABS, to provide advice to potential users of genetic resources, free-of-charge and on a confidential basis. We conducted 34 consultations in fiscal 2014 and has handled more than 510 consultations since establishing Help Desk in 2005.

Support for International Negotiations on ABS

JBA has supported the Japanese government in international negotiations on ABS. When the Nagoya Protocol entered into force in October 2014, we participated in the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP1) held in Pyeongchang, Republic of Korea



ABS open seminar



Guidelines on Access to Genetic Resources for Users, 2nd Edition (left) and its English translation (right)

Awards

JBA promotes scientific research that contributes to the growth and development of bioindustry by offering awards.

Japan Bioindustry Association Award

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|---|--|
| <p>■ Hiroyuki Mizuguchi
Osaka University</p> | <p>■ Generation of functional hepatocytes from human induced pluripotent stem cells and the application for drug toxicity testing</p> |
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Japan Bioindustry Association Award

Fermentation and Metabolism Research Award

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| <p>■ Shigenobu Kishino
Kyoto University</p> | <p>■ Development of functional fatty acids using gut microbial specific fatty acid metabolism</p> |
| <p>■ Shin Kurihara
Ishikawa Prefectural University</p> | <p>■ Discovery of novel polyamine metabolic and transport pathways and their application for human health</p> |
| <p>■ Motoyuki Shimizu
Meijo University</p> | <p>■ Epigenetic regulation of fungal metabolic genes by changes in intracellular redox balance</p> |



Fermentation and Metabolism Research Award

Award for Researches on Chemical and Biological Materials

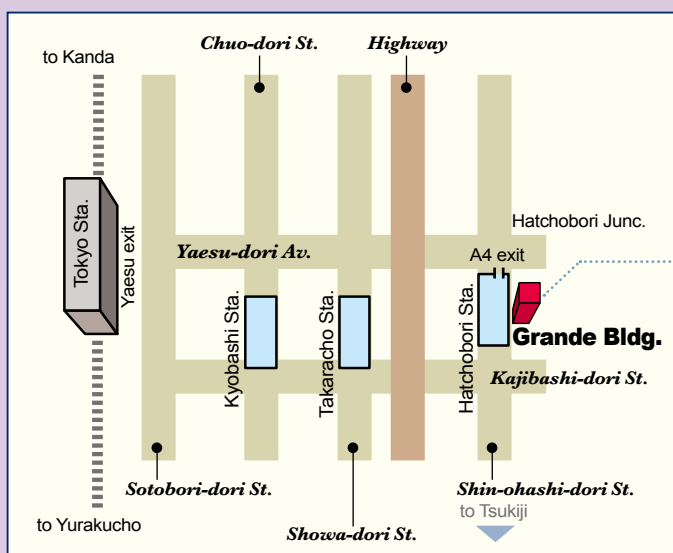
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| <p>■ Masato Ikeda
Gifu University</p> | <p>■ Development of hydrogels based on stimuli-responsive nanofibers for bio-applications</p> |
| <p>■ Hiroshi Nonaka
Kyushu University
(currently University of Tokyo)</p> | <p>■ Development of a highly sensitive platform structure for hyperpolarized magnetic resonance probes</p> |
| <p>■ Junji Fukuda
Yokohama National University</p> | <p>■ Design of zwitterionic oligopeptides for electrochemical cell detachment and its use for regenerative medicine</p> |



Award for Researches on Chemical and Biological Materials

access

A-4 Exit Hatchobori Sta. Tokyo metro Hibiya line



JBA

JBA website

<http://www.jba.or.jp/>

JBA invites members to make use of the seminars, video streaming, the Biotechnology School, and other diverse contents offered by JBA to promote bio-innovation.



privileges

I Subscription to JBA's journal, *Bioscience and Industry (B&I)*

- * Subscription to JBA's bimonthly journal *Bioscience & Industry (B&I)* is free.
- * Other JBA publications are available at a discount.

II Participation in JBA's Board of Directors, committees, study groups, etc.

Members of JBA's Board of Directors, committees, study groups, etc. are able to comment on JBA's operations and activities. (Specifics may differ according to member category.)

III Participation in policy measure recommendations, etc.

Members participating in committees, study groups, and other groups operated by JBA are able to deliberate, consider, and comment on government science and technology policy measures, national and local government regulations, etc.

IV Participation in events held by JBA

- * Members are able to participate at no cost or discounted cost in lectures, seminars, training courses, consultations, networking events, and other events held by JBA, and thereby have early access to up-to-date information on research and development and policy measures.
- * Members are able to access members-only materials on the JBA website and freely browse the above information and other content on JBA's activities.

V Participation in planning and proposal for national research and development projects

Members are able to participate in committees, study groups, etc. operated by JBA, and participate in drafting government research and development projects, drafting survey research projects, and proposing plans to relevant government ministries and agencies.

VI Use of seminar video streaming

Members are able to view a portion of JBA's lectures, packed with up-to-date information, via PC.



B&I is a bimonthly journal that provides members with easy-to-understand overviews of new and advanced academic articles in the field of bioscience, bio-related industry and government trends in Japan and overseas, and more.

Association of the members, by the members, for the members



Japan Bioindustry Association

Grande Bldg. 8F
2-26-9 Hatchobori Chuo-ku Tokyo 104-0032, Japan
TEL+81-3-5541-2731 FAX+81-3-5541-2737
URL: <http://www.jba.or.jp/>