

A New Age of Open Innovation Toward the Creation of New Bio-Business



Create the future

via bio-innovation



Japan Bioindustry Association

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: 192 companies
(pharmaceutical, food, chemical, cosmetic and machinery companies)

Public members: 97 organizations

Individual members: 818
(university and corporate researchers)

Budget ■ 700 million yen (2014)

Board of Directors

Chairman
Michio Oishi

Professor Emeritus,
The University of Tokyo,
President of KAZUSA
DNA Res. Inst.



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



JBA Activity Report 2014 contents

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Mission

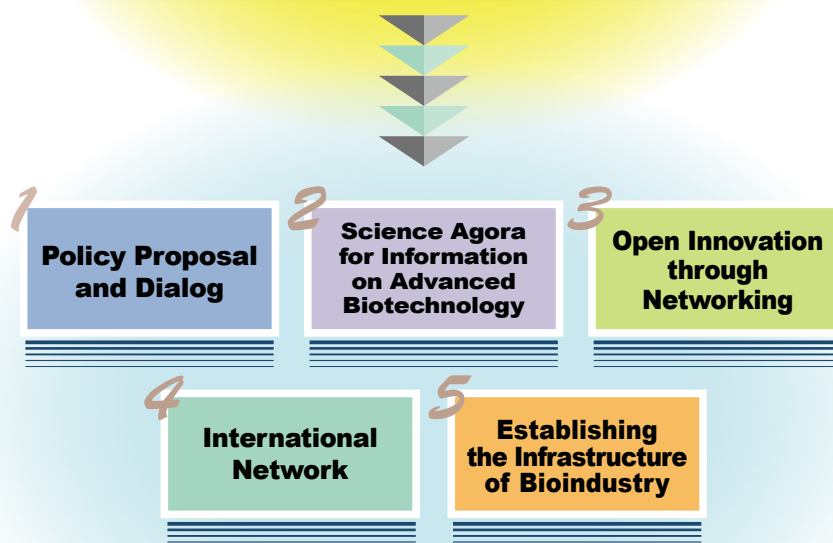
JBA contributes to bioindustry and related industries in the fields of health, environment and food

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 which 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

JBA has offered a variety of policy proposals and opportunities for dialog for the sound development of biotechnology and bioindustry in cooperation with member companies, universities, and government bodies.

In cooperation with the Japan Association of Bioindustries Executives (JABEX; Chairman Koichiro Aramaki), JBA aggregates comments from industry concerning science and technology policy measures and industry policy measures for bioindustry, and submits ongoing recommendations and comments. JBA also promotes dialog between the government and private sector, through means such as inviting persons in charge of drafting and enacting policy in government bodies to speak at government policy seminars.

The general meeting of JABEX (March 2014)



Accomplishment 1

Policy proposal

JBA and JABEX explained the Comprehensive Strategy for Bio-Innovation (interim) proposal document, created in March 2013, to Excutive Acting Secretary-General of Japan's Liberal Democratic Party Hosoda (Chairman of the Diet Members' Promotion Alliance for Life Sciences), as well as to Keidanren, members of government-related conferences, and staff of ministries and agencies.

Proposal on the Comprehensive Strategy for Bio-Innovation
(interim recommendation)



JABEX Chairman Aramaki, Excutive Acting Secretary-General Hosoda, JBA Chairman Oishi, JBA President Nagayama

Accomplishment 2

Participation in meeting of the Diet Members' Promotion Alliance for Life Sciences

JBA and JABEX were the private sector participants in the first

meeting of the Diet Members' Promotion Alliance for Life Sciences held in five years (November 2013), where JABEX Chairman Aramaki, JABEX Vice-Chairman Nagayama (President, JBA), and JABEX Excutive Director Oishi (Chairman, JBA) expressed opinions on 1) promotion of dialog with industry, 2) the need for grand design and hearings with front-line researchers, and 3) the importance of research on the food and environment sectors.

Accomplishment 3

Submission of comments to the regulatory reform hotline

JBA has submitted a 10-item opinion to the Cabinet Office's regulatory reform hotline. This addressed topics including regenerative medicine, individualized medicine, medical data, reform of the food for specified health uses (FOSHU) system, functional labeling of foods, bio-ventures, genetically modified crops, proper evaluation of innovation, and submission of applications related to the Cartagena Act. (October 2013)

Accomplishment 4

Government policy seminars

At each of these seminars, JBA invites persons in charge of drafting and enacting policy in government bodies as speakers, and promotes dialog and the exchange of ideas between the government and private sector. Seminars were held eight times in FY 2013, with speeches on topics including regenerative medicine (Ministry of Economy, Trade and Industry), research and development of food (Ministry of Agriculture, Forestry and Fisheries), strategies for health and medicine (Cabinet Secretariat), the Comprehensive Strategy on Science, Technology and Innovation (Cabinet Office), 6th industrialization and cooperation among medicine, welfare, food, and agriculture (Ministry of Agriculture, Forestry and Fisheries), and the Industrial Competitiveness Enhancement Act (Ministry of Economy, Trade and Industry).



2

Science Agora for Information on Advanced Biotechnology

JBA is addressing the provision of biotechnology and new technical information on the industry, along with the discovery of seeds and industrialization, in cooperation with member companies, universities, and government bodies.

JBA collects advanced biotechnology information in Japan and overseas, conducts research on the latest development trends, and discovers technical seeds that may lead to new industries. JBA shares the results among its members through lectures and seminars. Furthermore, JBA considers project concepts that should be deployed in cooperation with industry, government, and academia.

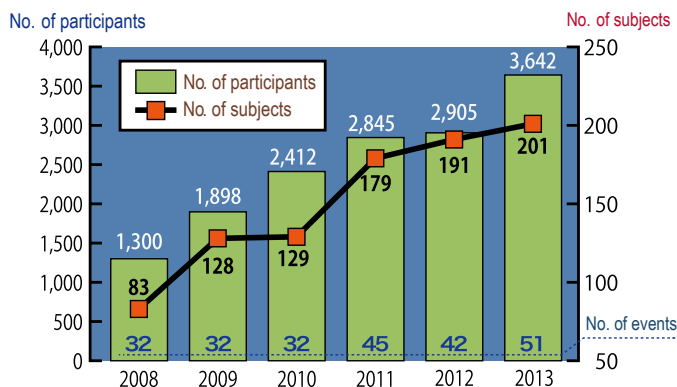
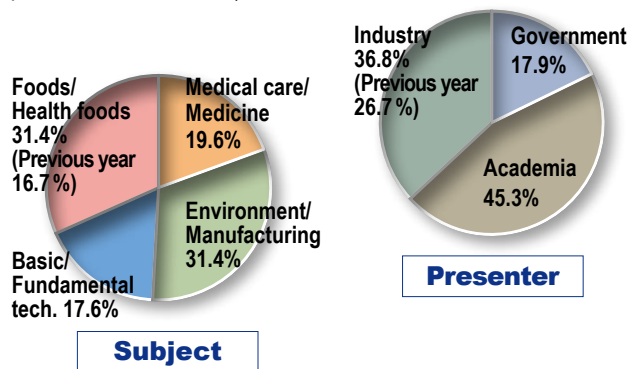
Accomplishment

In fiscal 2013, JBA hosted a total of 51 workshops, seminars, lectures, symposiums, and study tours. This schedule equated to some sort of event held nearly every week, covering 201 subjects and drawing 3,642 participants. Looking at events in technology fields, environmental- and manufacturing-related and foods/health foods subjects were greatest in number, followed in order by subjects related to medical care/medicine and basic/fundamental technologies. The percentage of subjects in the field of foods/health foods was 31.4%, up from 16.7% in the previous fiscal year.

JBA hosts opportunities for business card exchanges and socializing after lectures, and works to form networks among the participants to tie the seminars to business and market creation, policy recommendation, and business matching. JBA is also taking up overseas technology information and planning that offers new solutions, such as smart health care and smart devices. In addition to niche and compound domains, JBA hopes to combine bio with fundamental technologies that support cutting-edge science such as plasma, superconductivity, and neural science, and by doing so, to connect these to the creation of new business.

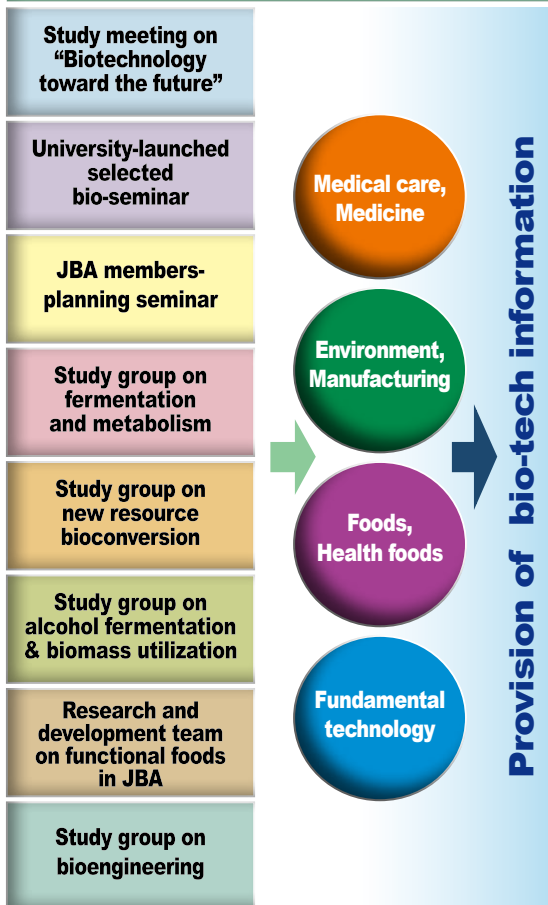
Work shops, seminars, lectures, etc: 51 Subjects: 201 Participants: 3,642

(April 2013 – March 2014)



Increase in seminars & audience (2013)

Bioseminar series activity



Enhancement of the field of foods and health foods

To advance the prosperity of the functional foods-related industry, JBA began by identifying issues concerning what can be done and what should be done. From there, it established a Research & Development Team on Functional Foods in JBA to conduct deliberations and investigations to resolve the issues, and to make proposals and recommendations to government. The Team also exhibited at BioJapan 2013, where many participants gathered for an event coordinated by the Team Chairperson Keiko Abe (Professor Emeritus, The University of Tokyo), titled "Functional Food Summit: What is a Next Step Board in Functional Food Industry."

JBA has submitted a summary concerning the food functionality labeling that is under consideration as a component of regulatory reform, and, through the Research & Development Team on Functional Foods in JBA, has submitted a document titled "Proposal for Regulatory Reform of the Functional Labeling System for Health Food" to Secretary General Anan of the Consumer Affairs Agency and the Head of the Japanese Ministry of Agriculture, Forestry and Fisheries Technical Committee Secretariat. JBA has also delivered opinions on these documents.



Prof. Keiko Abe



Booth of the Research & Development Team on Functional Foods in JBA

Hosting of large-scale symposia

On December 13, 2013, JBA held the large-scale symposium "GMP Progress and Single Use in Production of Biopharmaceuticals," attracting 142 participants. The symposium was sponsored by the Study Group on Bioengineering and focused on biopharmaceutical manufacturing, especially single-use technology. Speakers from four user pharmaceutical manufacturers, domestic and overseas suppliers, and engineering companies talked frankly about the current state of single-use technology and related issues. During the panel discussion, remarks from the floor led to an active discussion.



Panel discussion: "GMP Progress and Single Use in Production of Biopharmaceuticals"

Enhancement of membership privileges

After the conclusion of events, JBA promptly posted reports on its website and made presentation slides available as PDF documents, limited to JBA corporate and individual members. JBA also enhanced its video streaming service for corporate members, with a total of 31 seminars and 99 presentations available. In total, viewing requests have come from 230 persons, for 480 seminar videos and 1,514 presentation videos. JBA set a price differential between non-members and corporate members, and planned a closed seminar for members only. In addition, JBA conducted activities to bring together corporate member companies and university researchers, and also assisted the establishment of university endowed chairs by member companies.

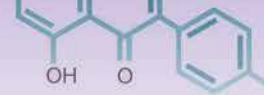
Foods/health foods (16 seminars)

JBA enhanced its seminars related to the analysis and scientific evaluation of functional foods. The Research & Development Team on Functional Foods in JBA held a closed lecture meeting on functional labeling in the U.S. and food labeling-related actions by the Consumer Affairs Agency, deepening understanding on these topics.

- Scientific evidence of functional food: Improvement of sugar and lipid metabolism (Dec.5, 2013)
- Rare Sugar, a dreaming bio material from the Kagawa University, for functional food and innovative drug (Jan.14, 2014)
- Immuno-stimulation, antioxidation, and anti-inflammation, key activities for functional food development (Feb.19, 2014)
- Site visit and lecture at Gekkeikan Okura Sake Museum (Feb.26, 2014)



Gekkeikan Okura Sake Museum



Environment, Manufacturing (16 seminars)

The origins of the Japan Bioindustry Association lie in manufacturing that makes use of microorganisms. JBA held events on strictly selected themes including biofuels, biorefineries, and cosmetics. Looking ahead, JBA will pioneer new businesses in response to requests from our members and from society, with green innovation as our area of focus. Among the themes we will take up are fuels made from bio-derived raw materials, chemical production technologies, and the use of algae.

- Truth of biomass utilization: How can we gather the wisdom of Japan? (April 24, 2013)
- New Developments in bio manufacturing: Perspectives of synthetic biological engineering (June 10, 2013)
- Recent trends of research in aquatic biomass refinery (Sept. 20, 2013)
- Many flowers blooming in profusion of biomaterial: Cosmetics for skin care developed by biotechnology (Jan. 30, 2014)
- Production of nano-cellulose fermentation from biomass and development of new high-performance polyester (March 14, 2014)



Prof. Yasuo Igarashi



Dr. Dai Kitamoto



Prof. Masahiro Samejima

Medical care, Medicine (10 seminars)

JBA took up a diverse range of topics related to medicine and pharmaceuticals. In the coming fiscal year, we will widen our vision to encompass the health care business, and will address a variety of topics including new diagnostic equipment, telecommunications for at-home medical examinations, and health maintenance businesses linked to exercise and meals.

- Drug Repositioning (The second meeting) (June 17, 2013)
- Tour of YBIRD (Yokohama Biopharmaceutical Research and Development Center) and RTD (Round Table Discussion) (July 17, 2013)
- Progress in GMP and single-use technology in biopharmaceutical manufacturing process (Dec. 13, 2013)



Dr. Shinichi Yachida



Dr. Takuji Yamada



Site tour of YBIRD

Fundamental technologies (9 seminars)

JBA addressed topics including synthetic biology, bio-resources, genetic testing, genomic engineering, and technologies to counter terrorism and crime. Our goal is to combine bio with advanced science and technology, and to connect these to the creation of new business.

- New winds from Bio-resources (May 20, 2013)
- To be right or left, that is the question: Cutting-edge research on D-amino acid physiology- (May 29, 2013)
- Prevention technology against crime and terrorism for the safe and secure society (Nov. 25, 2013)
- Japanese technology toward power-up of industrial microorganisms: Overview from the origin and recent innovative technology for breeding strains (Dec. 17, 2013)

To be right or left, that is the question: Cutting-edge research on D-amino acid physiology-



Prof. Mitsuo Kawase



Prof. Satoshi Harashima



Prof. Masaharu Ishii



Novel project planning

JBA conducted and sponsored study meetings and seminars for drug repositioning and construction technique for cell-multilayered tissues, with the aim of launching projects and establishing consortia. In the coming fiscal year, JBA will continue to work toward project launches.



Dr. Takeo Shimazaki



Dr. Tohru Natsume

Research & development projects

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

■ Research and Development of Valuable Technology for Biofuel Manufacturing from Cellulosic Biomass: NEDO (FY 2013-2016)

The Biofuel Technology Innovation Plan has set a goal of manufacturing liquid fuel from cellulose-based biomass resources, at ¥40/ℓ-EtOH with an energy recovery rate of 0.35, by 2015. JBA participated in the Basic R&D on Enzymatic Saccharification of Cellulosic Biomass and Biofuel Production project commissioned by NEDO for five years from 2008, setting and successfully completing a course toward the goals noted above. NEDO further announced the Project for Research and Development of Useful Elements for Biofuel Manufacturing, which aims to establish production technology with commercial-scale applications by 2020. JBA joined with research institutions to apply for two areas of the project, Development of Production Technology for Useful Saccharifying Enzymes, and Development of Fermentation Production Technology using Useful Microorganisms. JBA was selected for the project, and technological development began in mid-December of last year. In Development of Production Technology for Useful Saccharifying Enzymes, JBA is engaged in 1) functional enhancement of saccharifying enzymes, 2) creation of microorganisms for industrial saccharifying enzyme production, and 3) technology for low-cost mass production of saccharifying enzymes. In Development of Fermentation Production Technology using Useful Microorganisms, JBA is engaged in 1) development of microorganisms able to perform simultaneous fermentation of C5 and C6 sugars, 2) development of a simultaneous saccharification and multiple parallel fermentation process, and 3) research and development of process design packages.

■ Development of technology for new material recycling using superheated steam of plastic material containing natural-derived polyester resin for information appliances: Technological development: Kinki Bureau of Economy, Trade and Industry, (FY 2010-2013); PL Tadashi Yamamoto, Director, Naomoto Corporation)

For information appliance cases and components containing polyester-based bio-resins, JBA developed material recycling technology for acceleration of the hydrolysis reaction through superheated steaming, recovery of polyester resin alone as oligomers, and new recycling of the resin, and, for non-polyester-based resin, collection and reuse followed by recycling into the original cases or components with as little degradation as possible. Specifically, JBA developed a mass production prototype of high-efficiency, large-scale superheated steam treatment equipment (treatment capacity: 50-60kg of resin per batch), and worked to optimize resin as a material recycling input through the separation, collection, and recycling of the above composite resins.

■ Market and Technology Survey for Technology Research Association of Highly Efficient Gene Design: METI (FY 2013); Survey Committee Chair: Akihiko Kondo, Professor, Kobe University

To maximize the effects of this research project, which aims to create innovative biomaterial manufacturing technology, JBA conducted a survey of trends in domestic and overseas research and technology. In FY 2013, JBA conducted hearings of numerous researchers' opinions on conceptual differences between synthetic biology research and conventional recombinant gene technology, and, with the aim of extracting ideas for the progress of the research and development, conducted local overseas surveys (Pacific Rim Summit, J. Craig Venter Institute, U.S.), research and development trend surveys (collection and analysis of information including news releases and domestic and overseas papers and academic presentations), and surveys of existing literature.

■ Development of Evaluation Basis Technology for Practical Realization of Human Stem Cells: NEDO (FY 2010-2015), Stem Cell Evaluation Technology Research Association (allotted research; halted during (FY 2013))

JBA created a framework for an international standards proposal aimed at the standardization and industrialization of basic elemental technology (including large-scale *in vitro* automated processing and manufacturing technology for human iPS cells) involving clinical applications of regenerative medicine. Toward the acquisition of overseas markets in the field of regenerative medicine, JBA cooperated with the Forum for Innovative Regenerative Medicine (FIRM) to make an international proposal to ISO/TC 276 (Biotechnology) for the new establishment of a related task group, and received approval from the General Assembly (December 2013).

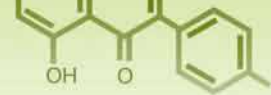


First General council of ISO/TC276 (Berlin)

■ Manufacturing Technology Association of Biologics (MAB): METI (FY 2014-2018); PL Takeshi Omasa, Professor, Tokushima University

This project, which gathers companies, universities, and public research institutions involved in biopharmaceutical manufacturing in Japan, was established for the purpose of conducting development of advanced and efficient next-generation technology for the manufacture of complex and multi-functional biopharmaceuticals (antibody drugs) in conformance with international standards. As an affiliate member, JBA is taking on overall surveying work, is constructing a prior patent database, and is investigating surveys on topics such as clearance of patent issues and identification of prior patents that may pose a barrier to research and development. In addition, JBA is collecting and analyzing literature surveys and other information pertaining to manufacturing methods that are largely kept secret as in-house expertise.

From here on out, JBA will work toward the communication of information that leads from the excavation of business seeds to actual business, and will advance the development of seminars and study groups.



3

Open Innovation through Networking

In alliance with member companies, universities, and the government, JBA provides opportunities to help the development of biotechnology and industry.

As an effective means for the promotion of alliances among relevant parties, the creation of opportunities for open innovation, and the construction of platforms for business, JBA holds the international comprehensive bio event BioJapan. Moreover, functioning as a hub through the Japanese Regional Clusters Forum, JBA aims to form networks among bio-related parties, and invigorate bio-ventures through mutual cooperation.

BioJapan

Japan's longest-running international comprehensive bio event, BioJapan has contributed to the development of bioindustry since its launch in 1986. From 2004, it has been held every year. BioJapan features exhibits, business talks, technical presentations by universities and venture businesses, and themed seminars.



Convenient web matching system

BioJapan also provides a system for arranging discussions with desired parties. "Matching members" are exhibitors and visitors requesting registration as matching members (fee required). Up to 45 meetings over the 3-day period are possible, supporting efficient business partner searches.

Step 1

Meeting requests

The system is usable from 2 months before the event. Participants record their own needs and business seeds in the system. Requests are sent to the desired parties for discussions.

Step 2

Set up appointments

The desired parties receive the requests and make provisional decisions. The system checks the schedules of both parties and, upon specification of an appropriate meeting date and time, sets the final schedule.

Step 3

Meetings

During the event, the registrant visits the specified booth to hold discussions with the other party.

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.

All Japanese Bio Regions Committee

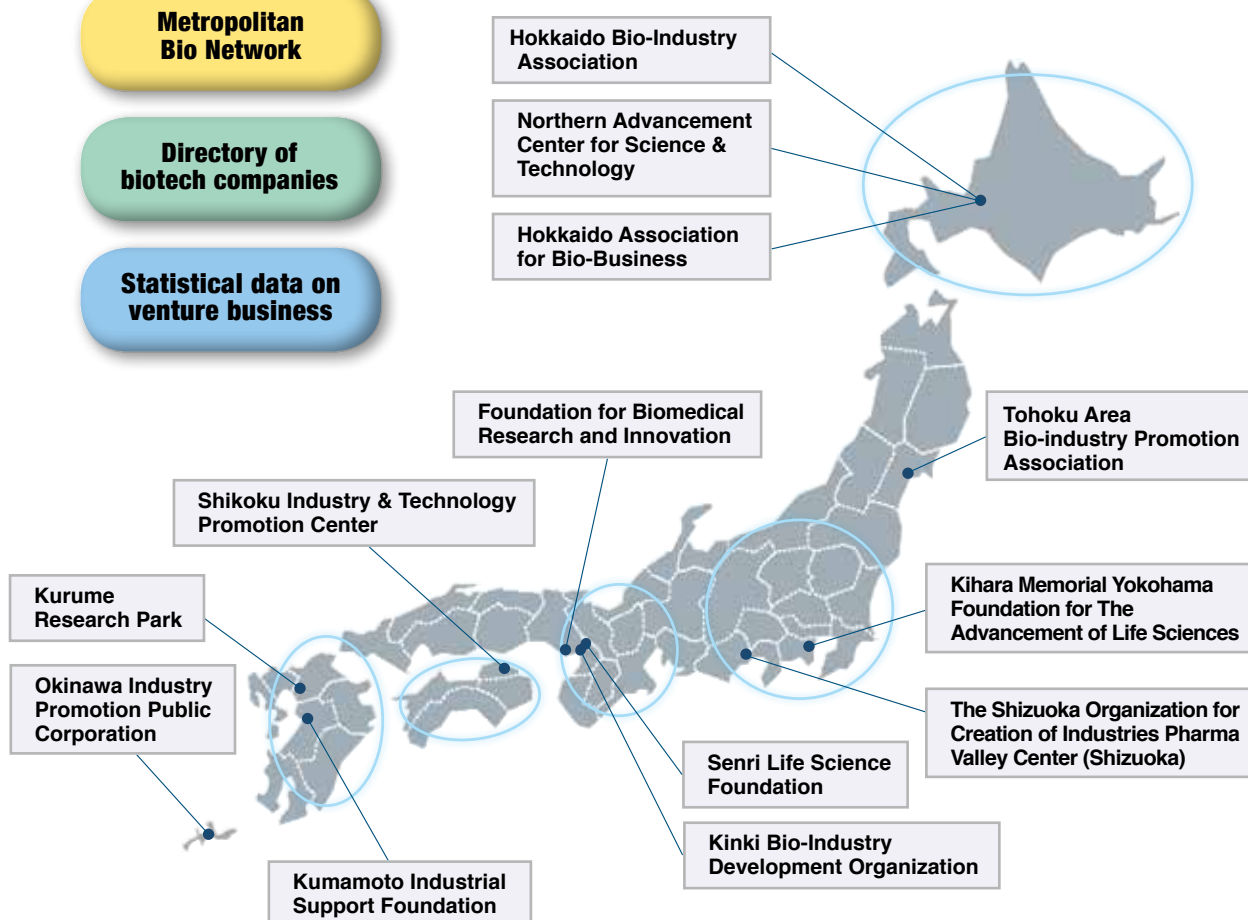
Support for overseas business of biotech companies

Metropolitan Bio Network

Directory of biotech companies

Statistical data on venture business

JBA launched All Japanese Bio Regions Committee in 2013 to promote communication and collaboration among bioclusters carrying out advanced initiatives across the country, as well as to promote the industrialization of local-based research outcomes and business seeds. Functioning as the hub for bioclusters through this conference, JBA aims to construct a space for collaboration at the national level while coordinating policy measures among cooperating industrial, academic, and government bodies, and also aims to create networks among bioclusters and invigorate bio-ventures through collaboration.



Accomplishment

1

All Japanese Bio Regions Committee (supported by Japan Pharmaceutical Manufacturers Association)

As a component of projects to form bioindustry networks that contribute to local revitalization, the Japanese Regional Clusters Forum 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. In particular, the Forum takes the viewpoint of international networking, with industrial, academic, and government bio organizations in Japan, Europe, the U.S., and Asia presenting the status of their activities and related issues, and deepening discussions.

Date: October 19, 2013

Organizing Committee: All Japanese Bio Regions Committee

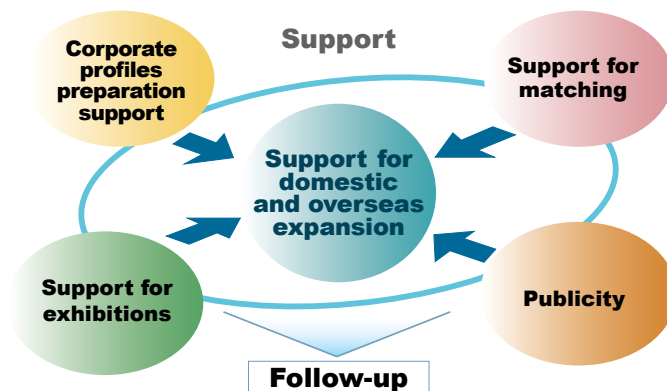
Subject: The Globalization of Cluster

Activities: Aiming for International Mutual Cooperation

Accomplishment 2

Support for overseas business of biotech companies business and cooperation with JETRO

The exchange of opinions and opportunities for interaction with worldwide bio-clusters can be an effective means to break through the bio-venture business environment, which tends to be opaque. Therefore, by endeavoring to promote cooperation with overseas major bio-clusters, JBA supports the matching of bio-venture companies and foreign corporations. Furthermore, in order to multilaterally and effectively lead the activities to results, JBA has promoted further cooperation through its activities with Japan External Trade Organization(JETRO). JBA has a close relationship with JETRO and supports bio-venture companies by participating in Bio-Europe Spring, etc. Cooperation with activities at JETRO BIOLINK, held concurrently with BioJapan, is another example of the establishment of a complementary relationship through mutual activities.



Accomplishment 3

Metropolitan Bio Network activity

Japan's nexus for bio-related industries, the Greater Kanto region is home to over half of the nation's bio-venture firms, as well as research institutions and universities possessing advanced technologies. As a component in industrial cluster planning, and with the aims of promoting collaboration among players in diverse fields and constructing rich personal networks to contribute to the development of bio-ventures, JBA has been active as the secretariat of Metropolitan Bio Network Japan, which was launched in July 2002. At present, JBA is focusing on technology transfer, encouraging expansion overseas, and promoting alliances with major companies and bio-ventures. It is undertaking activities such as seminars to support alliances and to resolve issues faced by venture companies, and is advancing policy measures to foster research and development and commercialization in areas including drug discovery.

Accomplishment 4

Preparation of directory of biotech companies

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.

Please click

[Bio Venture Directory](#)

at the JBA website.

Accomplishment 5

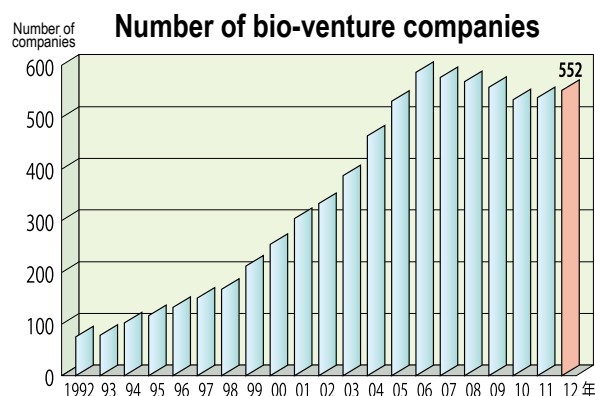
Preparation of directories and statistical data on bio-venture business

■ In January 2013, JBA conducted a questionnaire survey of bio-ventures across Japan and performed classification and statistical analysis of these according to prefecture and category. The results were gathered in "2013 Survey Report on Statics and Trends of Bio-venture companies in Japan".

■ There are 552 bio-ventures, a slight increase from the previous year. While 42 venture businesses were newly recognized in the past year (including newly recognized companies that were established in or before 2012), 6 companies underwent dissolution, absorption by merger, or other change, and 22 companies were excluded under the definition of bio-venture used by the survey, resulting in an increase of 14 companies.

■ Looking at movements surrounding bio-ventures, the number of incidents of joint research between bio-ventures and large or medium-sized companies, as well as licensing and agreements, remained stable. Performance measurements such as acceptance of milestones are on a rising trend.

■ JBA is also continuing its joint research with Hitotsubashi University, leading to the release of the working paper "The Science Sources of Bio-ventures and Issues in their Growth: Survey of 2012 Bioventure Statistics" on the Hitotsubashi University Institute of Innovation Research website.



4

International Network

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

As international activities, JBA communicates overseas bio-related information and introduces bio events to members, disseminates information on Japan's bioindustry, issues opinions on international issues as a bio organization in Japan, networks with overseas bio organizations through participation in international bio events, and solicits participation in BioJapan. While reflecting the views of its member companies, JBA performs work that is difficult to achieve for an individual company.

Accomplishment 1

Overseas bio-organizations having agreements with JBA

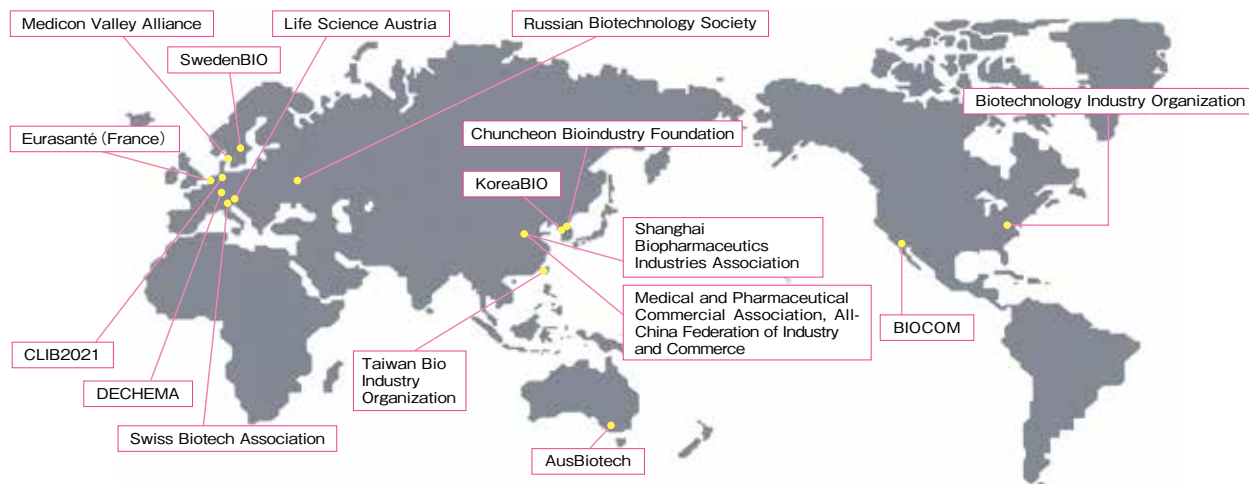
JBA conducts information exchanges with overseas bio organizations, embassies in Japan, and regional and state government bodies. Through its self- or jointly-planned seminars and JBA Public Relations, the organization promptly provides members with timely updates on overseas policy, investment environments, industry movements, research and development status, and other information that is difficult for companies to acquire.

31 members representing foreign agencies (Embassies, regions, state government etc.)

Australia, Queensland (Australia), Victoria (Australia), Austria, Flanders (Belgium), Wallonia (Belgium), Canada, Alberta (Canada), British Columbia (Canada), Quebec (Canada), Ontario (Canada), Denmark, Medicon Valley Alliance (Denmark/Sweden), Estonia, EU-Japan, France, Alsace (France), Germany, Ireland, Malaysia, Netherlands, Spain, Sweden, UK, Scotland (UK), U.S., Georgia (U.S.), Iowa (U.S.), Missouri (U.S.), North Carolina (U.S.), Pennsylvania (U.S.)

Overseas bio-organizations having agreements with JBA

- BIO (U.S.) (since 2004)
- Swiss Biotech Association (since 2005)
- Shanghai Biopharmaceuticals Industries Association (since 2005)
- Russian Biotechnology Society (since 2009)
- CLIB2021 (Bioclusters of the Rhein Region)/Cluster Biindustrielle Biotechnologie (since 2009)
- DECHEMA (since 2010)
- KoreaBio (since 2010)
- Medical and Pharmaceutical Commercial Association, All-China Federation of Industry and Commerce (since 2012)
- Medicon Valley Alliance (Denmark/Sweden) (since 2012)
- Taiwan Bio Industry Organization (Taiwan) (since 2012)
- SwedenBIO (since 2013)
- AusBiotech (since 2013)
- Chuncheon Bioindustry Foundation (since 2013)
- Life Science Austria (since 2013)
- Eurasanté (France) (since 2014)

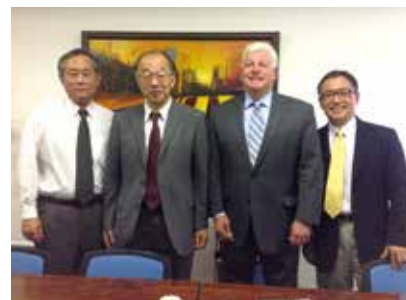


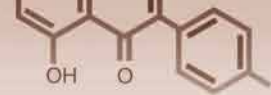
Accomplishment 2

JBA events and activities for open innovation in 2013

- Participation in BIO International Convention 2013 (Chicago, April)
- Participation in BioTaiwan 2013 and Asia Partnership Conference of Pharmaceutical Associations (APAC) (Taiwan, July)
- Participation in US-JAPAN Health Science DIALOGUE (Philadelphia, September)
- Participation in Ausbiotech (Brisbane, October)
- Participation in BIO-Europe® 2013 (Wien, November)
- Visits to the organizations promoting partnerships in Asia (Taiwan; Malaysia; Bangkok, Thailand) participation in Thai-Japan conference (November, in partnership with the Japan Pharmaceutical Manufacturers Association)
- Participation in BIOTECH SHOWCASE 2014 (San Francisco, January)
- Participation in BIO-Europe Spring 2014 (Turin) and visit to the Medicon Valley (Denmark, Sweden, March)

BIOTECOM





5

Establishing the Infrastructure of Bioindustry

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

With regard to the enactment process and management of various laws and regulations on bioindustry in the fields of food and environment, JBA collects and provides related information, and also holds explanatory meetings to collect and submit opinions from the industry. In addition, JBA establishes infrastructure for the development of bioindustry, such as promotion of national research projects through the management of research associations, the fostering of promising young human resources, and the awarding of research prizes.

Science/technology and laws/regulations

Accomplishment 1

JBA held an “Explanatory meeting on the utilization of the Cartagena Act”

JBA hosted overviews by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Economy, Trade and Industry on the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act), relevant points of note in situations such as industrial Type 2 use, and briefings on GILSP notification revisions, as well as a briefing by the National Institute of Technology and Evaluation on application procedures, initiatives to improve operations, and other topics. JBA also held post-briefing individual consultations.



Explanatory meeting on the utilization of the Cartagena Act

Accomplishment 2

Activities to promulgate biosecurity (creation of educational video)

JBA created and sold an educational DVD (Supervisor: Professor Nariyoshi Shinomiya, National Defense Medical College) aimed at enhancing the awareness and knowledge of researchers and managers concerning the biotechnology dual-use problem in new plant breeding techniques. (Jan. 30, 2014)



Educational video

Accomplishment 3

Cutting-edge biotechnology regulations and policy

In its *B&I* journal, JBA provided information on new plant breeding techniques that are receiving attention as breeding methods that do not leave traces of genetic manipulation in successive generations. JBA examined six issues in total, including the potential for the techniques and ideals for regulations on safe handling.

Science communication

Accomplishment 1

Publication of "Future Society Pioneered through the Contributions of Bio"

From last year, JBA has used **B&I** journal as a tool to communicate the organization's vision for a future society through bio (technology, lifestyles, and industrial development trends).

"Future Society Pioneered through the Contributions of Bio" ▶



Accomplishment 2

Seminars on communication of bio risks

(1) Issues in the Practical Realization of Genetic Modification Technology and Vision for Communication (July 29, 2013)

In this seminar, companies and research bodies with years of involvement in the application and industrialization of GM technology described how they have viewed and communicated to society the usefulness and risks of the technology. They presented examples from experience and discussed policies and measures that should be taken by industry in Japan.



Group discussion: Issues in the Practical Realization of Genetic Modification Technology and Vision for Communication

(2) Food Safety Considerations (Jan.20, 2014)

This seminar used examples such as BSE to discuss the evaluation and management of food risks, as well as how food safety should be communicated to society, and the policies and measures that should be taken by food-related parties.



Group discussion: Food Safety Considerations

Industry-academia communication and collaboration

To deepen industry-academia communication and collaboration, and to promote research and development and industrialization of biotechnology, a committee composed of experts from academic and corporate members is engaged in investigating 1) promotion of open innovation and industry-academia collaboration, and 2) ideal training and education for bio human resources.

Accomplishment 1

Promotion of open innovation, industry-academia collaboration, postdoctoral issues, and education for young researchers in the bio domain

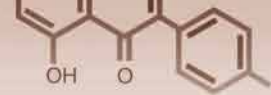
With regard to the promotion of open innovation, JBA continued to discuss topics such as the creation of venues for arranging collaboration among industry, government, and academia.

From the standpoint of introducing new open innovation systems to member companies, JBA invited Yutaka Teranishi of the Kyoto University Medical Science (KUMBL) and Business Liaison to discuss open innovation at the Kyoto University Graduate School of Medicine Medical Innovation Center, and invited Shinsuke Morisawa of the Kyoto University Center for iPS Cell Research (CiRA) and Application to discuss open innovation at that organization, along with discussions of systems at both institutions. With regard to postdoctoral issues and training for young researchers, the need for occupational reeducation to address supply and demand imbalance was discussed. (Feb. 17, 2014)

Accomplishment 2

The science sources of innovation (research cooperation)

The Hitotsubashi University Institute of Innovation Research carries out research on success stories in the field of the bio and pharmaceutical industries, with the aim of strengthening innovation capabilities in Japan by making recommendations for management and government policy. Together with the Office of Pharmaceutical Industry Research, JBA is cooperating on research to survey the background behind the birth of innovative pharmaceuticals. In FY 2013, JBA held the Seminar on the Source of Drug Discovery and Development, and made the presentation "Intellectual Property Competition and Initiatives toward Advanced Technology for Innovative Medicine." (May 13, 2013) Moreover, at the Incentives and Knowledge for Pharmaceutical Innovation symposium on industry-government-academia collaboration hosted by Hitotsubashi University (Sep. 26, 2013), JBA presented "The Launch of Innovative Pharmaceuticals and the Role of the Patent Protection: Lessons from the Cases of 11 Innovative Pharmaceuticals Discovered in Japan."



Biological resources and measures

Accomplishment

1

Support for international negotiations and awareness raising activities related to CBD/ABS

JBA has continuously supported the government in international negotiations such as the Conference of the Parties to the Convention on Biological Diversity (CBD) and the meeting of working groups on access to genetic resources and benefit sharing (ABS).

At the 10th Meeting of the Conference of the Parties to the CBD (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 (the Nagoya Protocol) was adopted. JBA translated it into Japanese and has contributed to enhance public awareness and understanding of CBD/ABS.



The Nagoya Protocol from CBD Secretariat (left) and the Japanese translation by JBA (right)

Accomplishment

2

Update of the Guidelines on Access to Genetic Resources for Users, based on the Nagoya Protocol

After the adoption of the Nagoya Protocol, JBA updated the Guidelines on Access to Genetic Resources for Users to incorporate principles of the Nagoya Protocol in 2012 (The Guidelines 2nd Edition). In February 2014, JBA issued its English translation.

JBA has held open seminars in major cities throughout Japan on a continuous basis to explain points to note on ABS based on the Guidelines 2nd Edition.



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

Accomplishment

3

Help desk for inquiries about ABS

JBA set up a help desk in April 2005 for consultation on issues and problems related to access to genetic resources.

Consultations are conducted in a confidential manner and the number of consultations conducted as of the end of FY 2013 exceeded 480.

Accomplishment

4

Activities for the domestic implementation of the Nagoya Protocol

Under the adoption of the Nagoya Protocol, consideration of the domestic measures toward ratification is proceeding in Japan. In August 2012, The ABS Committee of JBA member companies submitted its opinions regarding domestic implementation of the Nagoya Protocol in Japan to the Ministry of Economy, Trade and Industry.

In addition, JBA sent a committee member to the Consultative Committee on the Direction of Domestic Measures for the Implementation of the Nagoya Protocol that was convened by the Ministry of the Environment from September 2012 to March 2014, and provide the opinions from the standpoint of industry. Furthermore, JBA submitted a position paper in response to public consultation on the draft report of the Committee.

JBA will make every effort to ensure that the domestic measures in Japan could reflect the actual conditions of the access to genetic resources and should have high efficiency and cost-effectiveness in order to contribute to achievement of the objectives of the CBD and the Nagoya Protocol.

Accomplishment

5

Support for the international negotiation of MOP (the meeting of the Parties to the Cartagena Protocol*)

JBA is providing ongoing support to the Ministry of Economy, Trade and Industry in conjunction with the MOP7 international conference held in October 2013 in South Korea.

JBA conducted technical and expert analysis of movements in international deliberations over risk evaluation and guidance papers concerning modified organisms (living modified organisms or LMOs, defined in the same way as GMOs). JBA focused on the new guidance-related issue of synthetic biology, and summarized issues and policy measures to be taken into account by Japan from the standpoint of environmental impacts, laws and regulations, and other factors.

* **Cartagena Protocol:** A protocol (i.e., international convention) on securing safe transport, handling, and use of LMOs across national borders. It has been ratified by Japan.

Intellectual property

JBA is undertaking investigation of intellectual property rights and industry-academia collaborative activities, as well as intellectual property rights and the globalization of life sciences. Specifically, the Working Group on Intellectual Property Rights and Industry-Academia Collaborative Activities investigated topics including what evaluation standards public institutions use to determine support for the enhancement of universities' intellectual property rights, what companies desire from joint research with universities, and what companies expect with regard to intellectual property rights. In addition, the Working Group on Food Applications investigated the collection of patent information in health foods in China, based on the positioning of functional foods in that country.

JBA held a seminar on points of note for bio and life sciences companies with regard to the EU Unitary Patent System and Unified Patent Court, which are set to start next year. At the 11th annual research presentation of Intellectual Property Association of Japan, JBA's Working Group on Intellectual Property Rights and Industry-Academia Collaborative Activities held a research presentation. At the 2014 Life Science IP Forum held jointly with the Japan Pharmaceutical Manufacturers Association (JPMA), JBA held the event "The Contribution to Innovation of Global Health."

JBA also summarized the opinions of the U.S. Supreme Court and experts with regard to Myriad Genetics' gene patents, and reported the summary in **B&I**.

Human resource development

Accomplishment

JBA Bio-Leaders Course: Course on Business Planning in the Age of Open Innovation

With the usefulness of open innovation now widely recognized, there is a need for human resources able to properly evaluate outside technologies and advance research and development in partnership with outside institutions. Under that recognition, this course offers group work-based experience with creating new businesses from technology seeds.

Composition of the course program

1. Training in business planning (group work)
2. Lectures from company top management

Technology seeds: Commercialization planning is performed using actual patent applications submitted by universities and public research institutions in the technological fields of pharmaceuticals, medicine, chemistry, and food.



Group work

Awards

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

JBA Award in 2013

'Development of the next generation technology for secondary metabolite production' Haruo Ikeda, Professor

Fermentation and Metabolism Research Award in 2013

'Molecule breeding of an industrial cysteine producing microorganism by sulfur repression' Iwao Ohtsu, Assistant Professor

'Transport mechanism of membrane transporters and its application to industrial microorganisms' Kei Nanatani, Assistant Professor

'Development of yeast cell factories for ethanol production from lignocellulosic materials based on systems biology approach' Tomohisa Hasunuma, Associate Professor

Award for Researches on Chemical and Biological Materials in 2013

'Development of high-performance biosensors by nano-scale oriented-immobilization of sensing molecules' Masumi Iijima, Researcher

'Photo-reversible on-off recording of persistent room temperature phosphorescence' Shuzo Hirata, Assistant Professor

'Development of a highly selective oxidation process using binuclear iron monooxygenases for the synthesis of valuable chemicals'

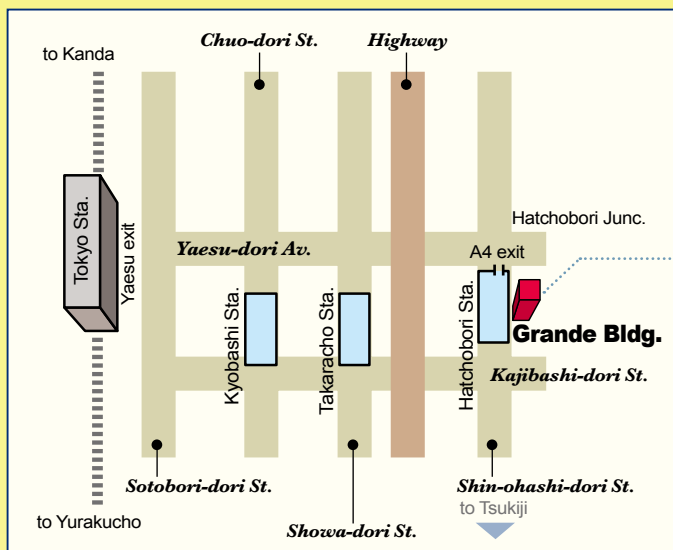
Toshiki Furuya, Assistant Professor

'Quantitative analysis of DNA-graphene interaction toward development of new biosensing platform' Daisuke Miyoshi, Associate Professor



access

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 content offered by JBA to promote bio-innovation.



privilege



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.

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.