Japan External Trade Organization I East Wacker Drive, Suite 3350 Chicago, IL 60601 Phone: 312-832-6000 Fax: 312-832-6066 www.jetro.org

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### Midwest U.S.-Japan Association Conference set for St. Louis

By Marie Gaudette, Executive Director, Midwest U.S.-Japan Association

The 48th Annual Meeting of the Midwest U.S.-Japan Association (MWJA) and the Japan-Midwest U.S. Association (JMWA) will take place **September 11 – 13, 2016** in St. Louis, Missouri.

MJWA has grown and evolved over the past 4 decades and we are pleased to convene for our 48th Annual Joint Meeting with our JMWA partners in St. Louis, Missouri this September. Our Associations have been committed to gathering each year to share common business strategies and develop strong linkages between participating companies and government agencies. This year's theme will focus on Innovation, Partnerships and Technologies for the Future as the common thread, entitled "Midwest U.S.-Japan: Gateway for the Future," and we have organized a series of Executive Panel Sessions and keynote presentations to focus on these themes in a variety of sectors.

The impressive participation of U.S. Governors for our 48th Annual Joint Meeting, led by our U.S. Chairman, Governor James Thompson,

See "Midwest U.S.-Japan Conference," page 5

### The Growth of Regenerative Medicine in Japan



From the Chief Executive Director

Ichiro Soné Chief Executive Director, JETRO Chicago It was no surprise that JETRO's Japan Pavilion at the BIO 2016 International Convention, June 6-9 in San Francisco, attracted many visitors. Japan is now the most business-friendly nation in the world for regenerative medicine.

TTER

IRO Chicago

In 2006, Dr. Shinya Yamanaka, a Japanese scientist, and his team discovered that common human cells can be turned into stem cells. Dr. Yamanaka was awarded a Nobel Prize in 2012 in Physiology or Medicine for

the work. So-called induced pluripotent stem cells (iPS) are now being used to replace simple tissues in the human body lost to disease or injury.

Under "Abenomics," Prime Minister Shinzo Abe's ambitious economic program, the Japanese government is striving to create the world's best business climate for regenerative medicine by promoting systemic reforms and facilitating market entry for foreign companies. With world-class iPS cell research already in place, we expect a substantial increase of opportunities in this industry.

See "Chief Executive Director," page 8

# **Missouri Governor Welcomes Conference**



On behalf of the six million citizens of the State of Missouri, I am proud to welcome everyone attending the 48th annual Midwest U.S. – Japan Association Conference in the great city of St. Louis from Sept. 11-13. For more than four decades, this event has provided a forum for business leaders and economic developers to strengthen ties and grow bilateral trade and investments between the Midwest and Japan.

I have had the privilege to participate in these

conferences in other Midwest states, and I know how valuable it is to meet face-to-face with our Japanese partners who represent government and business.

Japan and Missouri have a long established, and deeply valued, bond – educationally, culturally and economically, especially with Nagano, our sister state of 50 years. Culturally, one of the premiere attractions in St. Louis is the Japanese Garden at the Missouri Botanical Garden. This 14-acre garden, one of the largest of its type in North America, is a serene landscape that represents centuries of tradition and several distinct Japanese cultural influences. I invite those attending the conference in September to see this treasure.

Economically, as Missouri's largest trading partner in the Pacific Rim and our fourth largest trading partner overall, Japan plays a significant role in the success of our manufacturers and agricultural producers. For this we are grateful for our strong ties with our friends in Japan.

Each year, Missouri exports hundreds of millions of dollars in goods to Japan, including

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#### **JETRO in North Dakota**



On Thursday, May 12, JETRO Chicago and delegates from the Consulate-General of Japan in Chicago visited Bismark, North Dakota. Above left, Ichiro Soné and North Dakota Governor Jack Dalrymple.

(Above right, from left) K. Shirakura, Consul, Consulate-General of Japan in Chicago; Richard Stahl, Honorary Consul of Japan; Zoe Wergeland, Special Projects Coordinator, North Dakota Department of Commerce; John Schneider, Director, Agricultural Utilization Commission, North Dakota; Toshiyuki Iwado, Consul General of Japan in Chicago; Laura Willard, Business Development Manager, North Dakota Department of Commerce; Ralph Inforzato, JETRO Chicago; Brian Opp, Aerospace Development Manager, North Dakota Department of Commerce; Ichiro Soné, JETRO Chicago.



On Tuesday, May 17, South Dakota Governor Dennis Daugaard welcomed JETRO and the Consul General to his office in Pierre. (At left)Ichiro Soné, Governor Daugaard, Consul General Toshiyuki Iwado, Consul Keizo Shirakura.





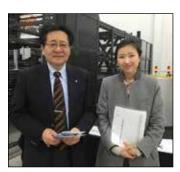
The Indy Chamber presented its World Trade Day event in Indianapolis onTuesday, May 24, and JETRO was on hand with a display.

At left, Japan America Society of Indiana's Chiaki Tokiwa and Jeremiah Maxwell with Kelly Highland of JETRO Chicago.



(Above left) On a June 22 visit to Madison, Wisconsin, Governor Scott Walker welcomed Ichiro Soné.

(Above right) Khay Khong, Market Development Director, Asia, Wisconsin Economic Development Corporation; Ichiro Soné, JETRO Chicago; Katy Sinnott, Vice President of International Business Development, WEDC; and Mark R. Hogan, Secretary and CEO, WEDC.



JETRO Chicago's Hyerin Childs made a visit to Elgin, IL for the Mazak Optonics Corporation's Innovation Days April 26 and April 27. Above, Ken Nakashima, Executive Vice President, Mazak Optonics Corporation with Hyerin Childs.



Ichiro Soné meets IndyCar driver Takuma Sato at the annual gala hosted by the Japan-America Society of Indiana (JASI) on June 15.



On May 6, JETRO Chicago's Daisuke Ito spoke on "The Final Rules of the FDA's Food Safety Modernization Act (FSMA)." The seminar attracted 30 attendees and was held in Chicago in cooperation with the Japanese Chamber of Commerce of Chicago (JCCC).



The Chicago International Trade Commissioners' Association (CITCA) visited Kansas City, MO, on June 17. Participants included Trade Commissioners from Belgium, Canada, China, Ecuador, Hungary, Macedonia, South Korea, Spain and Thailand, along with Ivry Karamitros from the World Trade Center Kansas City, and executives from Western Forms, Inc.

JETRO Chicago was represented by Akira Kawachi (second from left) and Hyerin Childs (front row, 4th from right).

#### JETRO in Wisconsin

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### Japan's Electricity Market Reform Creating Opportunities for All



**Daiki Nakajima** Project Manager, Business Development JETRO New York

**Guest View** 

The last time Japan deregulated the electric power market was 2005, when it expanded the retail competition for those with consumption of over 50kW. At the same time, the government established the wholesale power

exchange (JEPX) and its supporting body for transmission, hoping for sound competition in the power market. However, the government came to realize that throughout the years, there was not enough competition amidst the gradual deregulation of the electricity market since 1995 and found the need to open up the market by unbundling the incumbent utilities to further provide access to power producers and retailers.

The Great East Japan Earthquake of March 2011 changed the dynamics of Japan's economy as a whole. In the energy sector, there was a major shift in the generation mix as the government realized structural flaws in the power sector. As of June 2016, only two of Japan's 43 nuclear reactors are up and running, which has led to an increased reliance on fossil fuels. The government has also worried about peak load during the summer. In addition, an inefficient power grid model separating the East and West further complicated the situation. [Eastern Japan and Western Japan are separated by two different frequencies in the power grid (50 Hz in the East and 60Hz in the West).] Amongst other flaws, this ultimately led to Japan's need to fully deregulate the energy sector to create a balanced energy economy.

On April 1, 2016, Japan liberalized its electricity retail market creating a total market size of \$150 billion USD, making Japan one of the largest competitive energy markets in the world. This new market opens up significant potential for Japan to be a leader in the 21st century for new technology in the energy space. Similar to deregulation of the cellphone sector, a liberalized electric market will open doors for new competition and allow households to choose electricity from multiple power companies. To put it in perspective, 10 regional utility companies were

the only ones selling energy to the public; as of May 2016, there are more than 300 companies in this market competing for the same customers.

Those new entrants are offering discounted packaged services, combining other existing services like internet, reward points, even monthly train passes to lower the cost of electricity for households as well as luring in new customers from the existing utilities. According to the Organization for Cross-regional Coordination of Transmission Operators (OCTO), as of June 10, more than 1.1 million households have switched to a new power company, with 61% of those households located in Tokyo. Tokyo Gas and Osaka Gas are leading the pack, as they are anticipating the deregulation of the natural gas market in April 2017.

These reforms have also resulted in new investments from foreign companies. In preparation for the new electricity market, Texas-based power provider Spark Energy formed a joint venture with Tokyo-based power company eRex, forming eRex Spark Marketing Co., Ltd. in August 2015. Demand Response companies like EnerNOC, Opower, and Comverge are paving the way to offer services in the new market.

TEPCO is on a mission to procure smart meters from outside of Japan, as the country plans to install smart meters in all households by 2020. METI is also offering a subsidy program to encourage Net Zero Homes, or so-called Zero Energy Homes (ZEH), which potentially can integrate technology like battery storage systems, from foreign companies. In renewable energy, installation of rooftop solar systems has increased as Japan sees grid parity for small scale projects by 2019.

While change will not come overnight, competition in Japan is intensifying every month. It is likely that this reform will not see any major milestones for at least another year or two. Given the time and effort it takes to build relationships with Japanese companies, there is no better time to start engaging with people in Japan if your company is interested in doing business in Japan. And if so, there is no better place to start than JETRO.

Daiki Nakajima is a Project Manager at JETRO New York, responsible for promoting bilateral investments between US and Japan. Mr. Nakajima focuses on the healthcare, energy, IT, and agriculture sectors. He can be reached at Daiki\_Nakajima@jetro.go.jp.

### **Japan Festival**

The Japan Festival 2016 in Arlington Heights, Illinois took place the weekend of June 11 and 12 at the Forest View Educational Center and included entertainment, food and cultural exhibits. JETRO featured PARO, the robotic therapy seal, and promoted tourism in Japan in cooperation with the Japan National Tourism Organization (JINTO), which attracted many visitors to the booth.







#### **Meeting in Washington**

On June 21, JETRO Executive Vice President, Tatsuhiro Shindo met with Clayton Yeutter, former U.S. Trade Representative in Washington DC.



#### JETRO at Northwestern

On Thursday, April 7, JETRO Chicago's Robert Corder spoke to a group of graduate students at Northwestern University's Kellogg School of Management.

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### "Tremendous Success" at BIO 2016

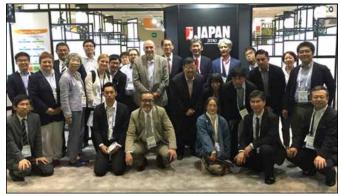
The 2016 BIO International Convention, held in San Francisco June 6-9, was deemed a "tremendous success" by Jim Greenwood, President & CEO of the Biotechnology Innovation Organization (BIO), organizer of the annual event.

This year, JETRO recruited twenty-two Japanese life science companies and research organizations to exhibit in the Japan Pavilion at BIO 2016. They presented new treatments for oncology, pain management, cognitive and neurological disorders; advancements in regenerative medicine; drug discovery tools; contract manufacturing; and R&D. Six of the companies exhibited in the Japan Pavilion for the first time:

- Hamamatsu Pharma Research, Inc., a contract research organization providing NHP testing as well as pharmaceutical drug development
- Nippon Chemiphar, a manufacturer of generic pharmaceuticals as well as proprietary drugs for treating hyperuricemia and inflammation
- Glycotechnica Ltd., which focuses on glycan structure analysis and related applications
- Okinawa Protein Tomography Ltd., a biotech company that aims to innovate the protein molecular structural analysis procedure without the crystallization process
- Itochu Chemical Frontier, a manufacturer of functional materials, pharmaceutical products and raw materials
- Gene Techno Science, a drug discovery company specializing in biologics and biosimilars

In addition, the Japan Agency for Medical Device Research and Development (AMED) participated in the Japan Pavilion as well. Launched in 2015, AMED promotes R&D in the life science sector, from basic research to clinical trials, establishing, maintaining, and providing funding for integrated R&D through to practical application. JETRO also coordinated booths for the Kobe Biomedical Innovation Cluster as well as a delegation from Osaka Prefecture.

During the convention, the Japan Pavilion delegates utilized BIO's Oneon-One Partnering system to arrange meetings. Over the course of three days, the Japan Pavilion exhibitors had a total of 570 business meetings,



Exhibitors and JETRO staff gather for a group photo at the Japan Pavilion.

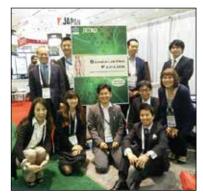
which are expected to result in 41 business agreements valued at more than \$3.9 million. On the opening day of the exhibition, JETRO hosted an exhibitor reception, welcoming visitors to the Japan Pavilion and serving a selection of sakes from Hyogo and Fukushima Prefectures.

At BIO 2016, JETRO also organized an education session on the impact of new medical regulations introduced in 2014 which were designed to speed up the approval process for innovative regenerative medical therapies. The session included speakers from JETRO, the Ministry of Economy, Trade and Industry (METI), and the Forum for Innovative Regenerative Medicine (FIRM), along with Ohio-based Athersys and Healios, a regenerative therapy company from Tokyo. Additionally, Ralph Inforzato, JETRO Chicago's Executive Director of Business Development, made a presentation during the Global Innovation Hub series.

As a part of the program, JETRO Chicago organized a partnering workshop for the Japanese delegates. Representatives from Horizon Pharma, Purdue Pharma, Bristol-Myers Squibb and Lonza Pharma & Biotech made closed-door presentations to the Japan Pavilion members. Speakers introduced their companies, detailed the therapy areas which they focus on, explained how they collaborate with other firms on research, licensing and marketing, and outlined the process for companies to connecting with them. Each workshop ended with Q&A as well as plenty of time for the Japanese delegates to network with the speakers.

If you are interested in learning more about Japan's life science sector or JETRO's biotech initiatives, contact Robert Corder at robert\_corder@ jetro.go.jp.





The Kobe Biomedical Innovation Cluster exhibit booth.

The Osaka delegation at BIO 2016.



Yoshiaki Tojo, Chief Executive Director, JETRO San Francisco; Osamu Nagayama, President, Japan Bioindustry Association (Chairman and CEO, Chugai Pharmaceutical Co., Ltd.); Ambassador Muriel Pénicaud, CEO, BusinessFrance; Hidetaka Nishimura, Director, Bioindustry Division, METI; Ichiro Soné, Chief Executive Director, JETRO Chicago.

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#### Japan Pavilion Exhibitors at BIO 2016

Cancer Profiling Discovery, Osaka University, www001.upp.so-net.ne.jp/CancerProfiling/index\_En.htm CellFree Sciences, www.cfsciences.com Chiba Cancer Center Research Institute, www.pref.chiba.lg.jp/gan/kenkyujo/institute/index.html Gene Techno Science, www.g-gts.com Glycotechnica Ltd., www.glycotechnica.com

Hamamatsu Pharma Research, Inc., www.hpharma.jp Hokkaido University Institute for Genetic Medicine, www.igm.hokudai.ac.jp/english/stemcell/index.html ID Pharma Co., Ltd., www.dnavec.co.jp

Institute of Development, Aging and Cancer (IDAC), www.idac.tohoku.ac.jp iPS Academia Japan, Inc., www.ips-cell.net/e/ Itochu Chemical Frontier Corp., www.itcchem.co.jp Japan Agency for Medical Research and Development (AMED), www.amed.go.jp Japanese Foundation for Cancer Research, www.jfcr.or.jp Kyoto University, www.kyoto-u.ac.jp/en

Nara Medical University, www.naramed-u.ac.jp NB Health Laboratory, www.nbhl.co.jp Nippon Chemiphar, www.chemiphar.co.jp Okinawa Protein Tomography, www.okinawa-pt.com Oncolys BioPharma Inc., www.oncolys.com/en/ Pola Pharma Inc., www.pola-pharma.co.jp RIKEN, www.riken.jp Tohoku University Graduate School of Pharmaceutical Sciences, www.pharm.tohoku.ac.jp

Osaka Prefecture Exhibitors AnGes MG., Inc., www.anges-mg.com/en Hamari Chemicals, Ltd., www.hamarichemicals.com Interprotein Corporation, www.interprotein.com Life Science Laboratories, Ltd., www.I-s-I.jp/english/ Osaka Prefectural Government, www.pref.osaka.lg.jp/en/index.html Strex, Inc., www.strexcell.com



JETRO presented a session, "An Update on Regenerative Medicine and Cell Therapies in Japan," at BIO's 2016 Conference on June 8. Speakers included Taku Sato, Director, Healthcare Industries Division, JETRO; Hidetaka Nishimura, Director of the Bio-Industry Division at the Ministry of Economy, Trade and Industry (Tokyo); Kunihiko Suzuki, Vice Chairman of the Forum of Regenerative Medicine or FIRM, (Tokyo); Dr. Hardy Kagimoto, President and Representative Director, Healios KK.; and Dr. Gil Van Bokkelen, Chairman & CEO, Athersys Inc., (Cleveland).



The Japan Pavilion at BIŎ 2016 featured exibits from twenty-two Japanese life science companies and research organizations.

Save the Date – BioJapan 2016 – October 12-14

Biotechnology, pharmaceutical and life science leaders from all over the world will meet in Yokohama for BioJapan 2016, scheduled to take place October 12-14. Organized annually by the Japan Bioindustry Association (JBA). BioJapan has become Asia's most important biotech event, with a large exhibition, conference sessions and pre-arranged partnering meetings. Last year, more than 700 exhibiting companies and 1200 partnering delegates participated in more than 6300 partnering meetings during BioJapan 2015. This year, the JBA is partnering with the Forum for Regenerative Medicine (FIRM) to organize the Regenerative Medicine Japan event. These two events will be collocated at the Pacifico Yokohama convention center.

For 2016, the U.S. Department of Commerce and the U.S. Embassy in Japan's Commercial Service are organizing a special U.S. Pavilion at BioJapan. In addition to access to BioJapan's partnering system, participants will exhibit in a special pavilion and have the opportunity to make a 10-minute company presentation during the conference. The U.S. Pavilion at BioJapan offers participants an excellent opportunity to network with top companies from Japan and Asia, to gain deeper knowledge about the Japanese market and to effectively promote their technologies and services to a high-level audience.

For more information about BioJapan or the Commerce Department's U.S. Pavilion at BioJapan, visit www.ics-expo.jp/biojapan/ or contact Ms. Tomoko Kikuchi at the BioJapan Secretariat at biojapan@jtbcom.co.jp.

#### Midwest U.S.-Japan Association Conference ... from page 1

will include but not limited to Missouri Governor Jay Nixon, Indiana Governor Mike Pence, Illinois Governor Bruce Rauner, Michigan Governor Rick Snyder and Nebraska Governor Pete Ricketts.

We are finalizing our roster of speakers from select corporations and organizations from the U.S. Midwest and Japan. Some of the presenters include H.E. Kenichiro Sasae, Japanese Ambassador to the U.S., The Boeing Company as our U.S. keynote presenter, Prolog Ventures, OCO Consulting, the Kauffman Foundation, Tovota Motor Company, Teijin Ltd, and Washington University. The final list of presenters will be updated on our conference website.

The main conference format has been structured to provide our delegates with ample opportunities to network with our Japanese partners at a senior level and MWJA is pleased to assist companies to connect with the appropriate delegates from Japan.

The Missouri Host Committee has been working diligently to organize the many details of this year's conference, including such events for the Sunday Program as Lunch and a viewing of the Cardinals vs. Brewers game at Busch Stadium, followed by our official Welcome Reception at the historic St. Louis Art Museum, located in the beautiful Forest Park area of St. Louis. Our Gala Dinner will be held on Monday evening at the beautiful Peabody Opera House in downtown St. Louis.

Our Annual Joint Meeting is always a special event for our Associations and we look forward to meeting with our friends from the Midwest region and Japan in St. Louis in September.

For further conference details, please refer to our web site at www.midwest.japan.org.

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### Guest View: Governor Nixon ... from page 1

chemicals, food products, and agricultural goods. In fact, agriculture has been one of the top economic sectors in our state for generations.

My administration has made connecting with our top export partners a top priority, especially our friends in Japan. And through some of our most recent initiatives, we have continued to grow closer every year.

Through Export Missouri, we support companies that participate in trade events and shows like the Japan Aerospace Show and the Japan Home and Building Show, providing opportunities to work together face-to-face with our Japanese trading partners. These Missouri firms recognize the incredible opportunity that the Japanese market represents, and as a state, we are committed to helping our businesses connect with those in Japan.

In addition, Japan is one of Missouri's strongest investment partners, with over 80 Japanese facilities located in Missouri, employing thousands of our citizens. Missouri's highly skilled workforce, probusiness climate, and strong conservative ethics provide a familiar culture for the Japanese companies – from Hitachi to Kawasaki to Toyota to dozens of others – who have a strong presence in our state.

As a state, we invest in education and workforce training to make sure our workers have the skills that Japanese companies need to produce some of the best products in the world. Our commitment to hard work and fiscal discipline, combined with a willingness to embrace bold ideas and innovative partnerships, makes Missouri a great place to do business.

This September, we welcome the opportunity to showcase what Missouri offers our friends from Japan. We look forward to seeing everyone there.

JETRO Chicago's Ichiro Soné attended the National Governors Association 2016 Summer Conference in Des Moines, Iowa from July 14-16.



Soné with Iowa Governor Terry Branstad.



From left, M. Yokota, President, JETRO NY; KY Governor Matthew G. Bevin; Shinji Hirai, Governor, Tottori Prefecture, and Ichiro Soné.



Soné with Iowa Lieutenant Governor Kim Reynolds.



Soné with Jay Byers, CEO, Greater Des Moines Partnership.



business information across Japan is better than ever. When you need information about regions, cities and prefectures, head to the Regional Information guide on the JETRO headquarters website. You'll find in-depth profiles of Japan's regions, highlighting major industries and clustersincluding size, attractive features and level of R&D functions-as well as other aspects of the general business environment. It's all easily accessible using an interactive map. Just click on the area or city of which you have an interest, and discover a wealth of information including regional

incentive programs and links to sources of local details.

The Regional Information site can be found at: https://www.jetro.go.jp/ en/invest/region/







### Contact JETRO Chicago • www.jetro.org INVEST JAPAN

**JETRO Chicago** is located at 1 East Wacker Drive, Suite 3350, Chicago 60601. Phone: 312-832-6000; Fax: 312-832-6066

For general information, call the number above.

The JETRO Chicago team offers a wide variety of business support services for companies in the Midwest planning to initiate a business presence or seeking to add to their existing investment in Japan, and/or work with Japanese companies. Please feel free to contact us.

Ralph Inforzato, Executive Director of Business Development, ralph, inforzato@iatro.go.in

ralph\_inforzato@jetro.go.jp Akira Kawachi, Director of Business

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**Robert Corder**, *Biotechnology & life science* and business service inquiries, robert\_corder@jetro.go.jp

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**Stephen Vullo,** *Industrial machinery exports from Japan inquiries,* 

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Hyerin Childs, Business Development Representative, hyerin\_childs@jetro.go.jp

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### **Program to Increase Foreign Entrepreneurs in Tokyo**

In May, a program making it easier for foreign nationals to start up business in Tokyo was launched. Previously, foreign nationals wishing to start up business in Japan needed to obtain a "business manager" visa. To obtain this status of residence, the applicant must employ at least two people full-time, or invest at least 5 million yen in Japan in addition to opening an office. This typically meant foreign entrepreneurs needed to do a great deal of advanced preparation before entry into Japan. Starting up business without a Japanese partner presented a high hurdle to foreign entrepreneurs.

Now, to provide smoother business startups by foreign nationals, the Tokyo Metropolitan Government launched a new program. Through this new program even an applicant who doesn't fulfill the above requirements at the time of the entry can obtain a status of residence (business manager) for the first half a year after entry, if the Tokyo Metropolitan Government can confirm that the applicant has enough prospects for fulfilling the conditions within half a year after entry.

For more details, please visit: http://www.seisakukikaku.metro.tokyo.jp/ invest\_tokyo/english/invest-tokyo/fhr.html

### Subsidy Program for New Business Establishment in Recovering Areas Continues

METI has started the Sixth Offering of Subsidies, for the Subsidy Program for New Business Establishment in the Areas Recovering from Tsunami and Nuclear Disaster towards Employment Creation (Manufacturing business site location support project).

The program is for establishment of new factories (manufacturing), distribution facilities, research laboratories, call centers, data centers and others, so as to activate the regional economy through employment creation in the areas within prefectures inundated by the tsunami and Tohoku Earthquake and the areas in Fukushima prefecture affected by the nuclear power station accident and where the evacuation order has been lifted.

The rate of subsidy depends on the size of the enterprises making investment. Subsidies up to 1/3 of the investment is offered for big businesses and up to 1/2 for SMEs, with a maximum subsidy of 3 billion yen.

For information, visit https://www.jetro.go.jp/en/invest/incentive\_programs.html#gov.

### **Free JETRO Webinars**

JETRO San Francisco has begun holding regular webinars about doing business in Japan. Each webinar focuses on a different industry sector or theme. Two webinars have been held so far, exploring opportunities in Japan's healthcare and energy markets. The next webinar, scheduled for Thursday, July 14, is entitled Three Keys to Success in Japan: Legal, Tax and Labor Management. This will be followed by a webinar on Thursday, July 21 discussing opportunities in Japan for companies with products in the Internet of Things (IoT) sector.

To register for these webinars, or for more information about future events, visit the Events section of the JETRO website, at http://www.jetro.org/usa/events.html.



Kohei Okui



Akira Kawachi

# Farewell and Welcome

In April, JETRO Chicago bid farewell to Kohei Okui, Director of Business Development. Mr. Okui arrived in Chicago in November 2012 and headed JETRO Chicago's efforts to promote inbound foreign direct investment to Japan from the Midwest. Mr. Okui returned to JETRO Tokyo and is now responsible for organizing Invest Japan seminars all over the world.

Taking over for Mr. Okui is Akira Kawachi. Mr. Kawachi is a native of Tokyo and attended Sophia University, where studied international law. He joined JÉTRO in 2006 and was assigned to the Information Systems Division where he spent four years. In 2010, Mr. Kawachi was transferred to JETRO's Design & Lifestyle Goods Division, where he helped Japanese companies grow their international exports. From 2014 through 2016, he served as the Director of the JETRO office in Sendai city, Miyagi prefecture. During his two years in Sendai, Mr. Kawachi assisted local companies as they worked to rebuild following The Great East Japan Earthquake of 2011. Mr. Kawachi can be reached at akira\_kawachi@jetro.go.jp.

In July, JETRO Chicago's Director of Agriculture & Research Daisuke Ito will also return to Japan. Mr. Ito will resume working at the Ministry of Agriculture, Forestry and Fisheries (MAFF). During his tenure in Chicago, he worked to promote food and agriculture exports from Japan to the USA. Over the past three years, Mr. Ito also did a great deal of work explaining the Food Safety Modernization Act (FSMA) to companies in Japan.

Ken Kasahara has been named as Mr. Ito's successor. Mr. Kasahara joined MAFF in 2006 after graduating from Keio University with a law degree. Since 2014, he has served as a Deputy Director in the Banking Division of the Japan Financial Services Agency (FSA), where he was responsible for supervising major Japanese banks. Besides his professional interest in financial and food markets, Mr. Kasahara is a big fan of basketball and is looking forward to cheering on the Chicago Bulls. Mr. Kasahara's new email address is ken\_kasahara@jetro.go.jp.

Everyone at JETRO Chicago wishes Mr. Okui and Mr. Ito the best of luck in their new positions back in Japan.



Daisuke Ito



Ken Kasahara

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The government is promoting the commercialization of regenerative medicines by implementing accelerated approval systems, as well as systemic reforms for the procurement of raw materials.

As a first step, both the Pharmaceutical Affairs Act and Regenerative Medicine Safety Act were enacted in November 2014, with regenerative medicine treated separately as items for cell therapies (rather than as medical instruments or pharmaceutical products). This means that products can be conditionally released to the market once they are approved as safe and there is an estimate of their efficacy. This shortens Phase III testing, which allows market release of the product in as little as 2 to 3 years, making it the fastest approval process among Japan, the U.S. and Europe. This system is driven by the desire to commence use once product safety is confirmed, since there are individual differences in the period for self-healing and the effects attributed to cell therapies.

Furthermore, Japan has nurtured an environment that facilitates the growth of regenerative medicine by making it eligible for some insurance claims, subject to conditional approvals.

At the same time, notification and approval of all regenerative medicine, including treatment not covered by medical insurance, is mandatory. This way, the quality of regenerative medicine can be assured, as the system weeds out those products with unknown efficacy. Previously, medical institutions had been required to manage cell culturing by themselves even if the field of regenerative medicine fell out of their area of expertise, but they will now be able to outsource cell culturing to specialist institutions. Medical institutions will be able to procure high-quality cells, and at the same time, reduce costs while allowing physicians to focus on medical practices. This signifies the growing need in Japan for cell cultures, and is not limited to consumables such as culture medium and culture vessels, where foreign companies excel. It also expands the scope of entry by related device companies, subcontract manufacturers and specialty logistics companies that transport the goods.

Japan is also promoting both domestic and foreign procurement policies in relation to raw materials. In April 2015, the government's Council for Regulatory Reform announced a policy to deregulate the import of frozen cells for research purposes. The Ministry of Agriculture, Forestry and Fisheries (MAFF) will also abolish the requirements for some documentary evidence for imports, which will make it easier for universities and manufacturers to import cells from overseas cell banks for testing in Japan.

In addition, the Ministry of Economy, Trade and Industry (METI) and the Ministry of Health, Labor and Welfare (MHLW) are working on policies and standards for providing cells in Japan to promote domestic procurement. To date, the Japanese market has relied on imports of human cells and ES cells from overseas companies. We expect increased procurement from both overseas and domestic companies in the future.

A newly established business association – the Forum for Innovative Regenerative Medicine (FIRM) – also assists the entry of foreign companies with an inquiry desk for commercialization of regenerative medicine. JETRO is working closely with FIRM to assist foreign companies' entry into the Japanese market.

Foreign-owned companies are actively looking to leverage the fast

approval system and apply iPS cell research to drug discovery, which is accelerating their entry into the business. Through the strengthening of both R&D and commercialization, Japan aims to become a leading market for the world's regenerative medicine industry. I will give you some examples: Lonza (Switzerland) is preparing to manufacture cells of regenerative medicine therapeutics through an alliance with Nikon. Pluristem (Israel) and ReNeuron (UK) will commence clinical trials of cell therapies soon. Bayer (Germany) and Novartis (Switzerland) have established offices in the Kansai region, where progress is being made in regenerative medicine R&D.



JETRO Chicago's Ichiro Soné and Ralph Inforzato welcome Holly Vineyard, Deputy Assistant Secretary of Commerce for Global Markets, U.S. Department of Commerce, to the Japan Pavilion at BIO 2016.

If we include products from Japanese companies, there are many more items considered to be regenerative medicine already undergoing trials or being submitted for approval. The successive release of products to the market, along with enhanced approvals, will also increase the business opportunities for companies providing support to manufacturers. In September 2015, two regenerative medicine products were approved a year after they were submitted for review under the new regulation: Terumo's autologous skeletal myoblast sheets and JCR Pharma's allogenic mesenchymal stromal cell (MSC) product. The entire process from application to approval had taken at least three years before, but the government has been able to whittle that down to just one year.

Japanese companies and research institutions are actively conducting clinical trials of regenerative medicine including RIKEN and The Center for iPS Cell Research and Application (CiRA), where Dr. Shinya Yamanaka is the Director. Therefore, we expect further expansion of regenerative medicine using iPS cells.

When Prime Minister Shinzo Abe embarked on "Abenomics," he declared, "As Japan will occupy a foremost position globally as society ages, we will be in a fortunate position compared to other countries when it comes to devising services, industries, and technologies suitable for a matured society." Developing the regenerative medicine industry is the key to realizing this concept.

Japan's life science market is already the second-largest in the world after the U.S., accounting for 10% of the global market for drugs and medical devices. Japan's life science market has been expanding every year due to the country's growing elderly population, and foreign life science companies are enjoying the benefits of this growth. According to Datamonitor, the Japanese biotechnology market had total revenues of US\$43.3 billion in 2012, and is expected to grow to US\$ 53.8 billion by 2017. A report from the Ministry of Economy, Trade and Industry (METI) calculates that the market for regenerative medicine will reach US\$8.6 billion by 2030.

If you can, please visit BIO Japan 2016/Regenerative Medicine Japan 2016 from October 12-14 in Yokohama, Japan and experience the dynamic Japanese market for yourself.