



U.S. Commercial Service Japan  
*Embassy of the United States of America*



*Tokyo, Japan*

July 2024

Dear All

The Commercial Service of the U.S. Embassy in Tokyo provides a variety of support for promoting exports of U.S. products and services to Japan. Since 2011, we also started assisting Japanese companies to invest in the U.S. by serving as the contact point of the investment promotion program called “Select USA.” The U.S. Embassy and Select USA is committed to providing Japanese companies with up-to-date information about investing in the United States.

As part of this program, we are pleased to announce that we will be sponsoring the 11th “US Medical Device Market Entry Seminar - US Market is Your Gateway to the World -” on Friday, September 6, hosted by GLOBIZZ CORPORATION of Los Angeles, California, an expert of the U.S. healthcare market and FDA application.

The United States continues to be the largest medical technology market and the most important market for Japanese healthcare-related companies. The “Medical Device Industry Vision 2024” released by the Ministry of Economy, Trade and Industry this March also indicated that the importance of developing the global market, especially the U.S. market, which is the largest market in the world, as a direction that domestic medical device manufacturers should aim for.

In this seminar, we will give presentations regarding the importance of obtaining FDA approval. Not only a US-based consultant will give a lecture on the latest trends in FDA regulations and key points of the US medical device business but also a European consulting company will explain an overview of the European Medical Device Regulation (MDR) and the benefits of having FDA approval when getting an approval in Europe.

The U.S. Embassy and Commercial Service hopes that this seminar will be a meaningful for all those who are considering expansion into the U.S. healthcare market, as well as for companies interested in the potential of the U.S. market.

We kindly ask you to register by the registration deadline.

Sincerely yours


Senior Commercial Officer,  
U.S. Embassy in Tokyo  
Daniel Lew

(Note: This is not an endorsement or recommendation of the relevant company as a U.S. government agency.)

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# 11<sup>th</sup> “U. S. Medical Device Market Entry Seminar”

## - US Market is Your Gateway to the World -

■ Date and Time	September 6 <sup>th</sup> , 2024 (Fri) 15:00 ~ 18:00		
■ Place	OTEMACHI FINANCIAL CITY, GBHT 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, JAPAN <a href="https://www.gbh-tokyo.or.jp/access">https://www.gbh-tokyo.or.jp/access</a>		
■ Host	GLOBIZZ Corp.		
■ Co-host	Globizz Japan		
■ Sponsor	U. S. Embassy in Japan, Qtics Medical		
■ Target Participants	Medical device manufacturers and their affiliated organizations *Please do not apply from companies in the same industry or companies competing with the host.		
■ Participation Fee	Free		
■ Language	Japanese, English		
■ Seating Capacity	100 seats		
■ Registration	from the link	<a href="#">👉 お申し込みはこちら</a>	Or from the QR 
■ Registration Deadline	Friday, August 23 We will close as soon as the maximum number of participants is reached. Please note that we may not accept more than one person from a single company if the number of participants reaches the maximum number.		
■ Inquiry	<u>About the Seminar:</u> GLOBIZZ CORPORATION Ms. Nagao Email: <a href="mailto:tokyo@globizz.net">tokyo@globizz.net</a> <u>About seminar registration:</u> U. S. Embassy, Commercial Service Mr. Hanawa Email: <a href="mailto:hiroyuki.hanawa@trade.gov">hiroyuki.hanawa@trade.gov</a>		

### ◆ Program ◆

15 : 00	<b>Opening remarks by Globizz Corp.</b>
15 : 05	<b>Greetings from the U. S. Department of Commerce and Introduction of Select USA</b> • • • U. S, Embassy, Commercial Service
15 : 10	<b>Attractiveness of the U. S. Market and Key Points of the U. S. Medical Device Business</b> • • • Globizz Consulting (U. S.) Takahiro Haruyama, President ➤ Key points of the U. S. market and the U. S. medical device business, and points to keep in mind when considering expansion to the U. S. market
15 : 30	<b>FDA Consulting by Physicians</b> • • • Globizz Consulting (U. S.) Tomoko Asagami M. D., Ph. D, M. B. A, Lead Researcher ➤ FDA regulatory overview, key points for FDA approval, FDA latest trends
15 : 50	<b>Overview of European MDR/IVDR and the advantage of having an FDA Approval when Entering the European Market</b> • • • QTICS Medical (Hungary) Tóth András
16 : 10	<b>Quality System Regulation (QSR) and FDA Inspections</b> • • • Globizz Japan (Japan) Miyuki Nagao, Senior Manager ➤ FDA inspection process and latest trends, overview of QSR and key points, transition to QMSR
16 : 30	<b>Introducing Globizz Services</b>
16 : 35	<b>Q&amp;A Session</b>
16 : 55	<b>Closing Remarks</b>
17 : 00	<b>Business Card Exchange and Networking Event</b>

This event, sponsored by the U.S. Embassy, Commercial Section, is for Japanese companies that are considering importing U.S. products or services in the purpose of supporting the relevant U.S. company' s business activities in Japan, but does not constitute an official endorsement, certification, or recommendation of the company, its products or services by the U.S. government agency.