SPECTARIS
Deutscher Industrieverband für Optik, Photonik, Analysen- und Medizintechnik

INVITATION

Your SPECTARIS contact:

Stefan Cieslak

Foreign Trade and Export Promotion

Tel. +49 30 41 40 21-46
Cieslak@spectaris.de

Regulatory Update Japan
Zoom – 09.05.2023
09:00 – 10:00 CET

Registration
Please register here

Participation fee
Participation is free of charge

Registration deadline:
Registration ends on the 05.05.2023

Webinar on the 9th of May 2023 | Zoom

Regulatory Update Japan – Overcoming challnges and working with the Pharmaceuticals and Medical Devices Agency

The Japanese medical device market is one of the world's largest markets for medtech. Fitch Solutions estimates a compound annual growth rate of 5.9 percent from 2021 to 2026. But which regulatory aspects must be considered when entering the market? What regulatory changes have been made recently? And how can interaction with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) be organised effectively?

These and further questions will be answered during our free webinar. We are pleased to welcome Dr Miyuki Shimizu (Medical Lab Partners) and Philip O'Neill (Parkdale Group Inc.) as speakers.

During this webinar, our speakers will share their insights on the Japanese market from a regulatory perspective. They will also provide a quick outline of the regulatory system in Japan, including the PMDA/MHLW and Notified Bodies, and how the PMDA differs from the FDA.

You will also learn about JMDN codes and their differences from EU and USA, as well as the role of the D-MAH or MAH in Japan. Our speakers will further discuss interactions with the PMDA, including initial meetings, development meetings, efficacy and safety, and challenging points for overseas companies in relation to the PMDA, such as testing protocols, low powered clinical studies, and differences from predicate devices.

The webinar will take place on Tuesday, 09.05.2023 from 09:00 to 10:00 CET via Zoom. Participation is free of charge. The registration form can be accessed here. Please register by the 5th of May.

We look forward to your participation and will be very happy to answer any questions you may have.

With kind regards,
Stefan Cieslak

In cooperation with:

MEDICAL LAB partners

PARKDALE GROUP
Japan Market Entry Experts

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Program:

- Overview on the Japanese market: Size, loyal customers, good regulatory system
- Quick outline of the regulatory system in Japan: PMDA/MHLW and Notified Bodies. How is PMDA different from FDA or EU?
- What are JMDN codes, how are they different from EU and USA.
- Role of the D-MAH or MAH in Japan - Why this is important
- Interactions with the PMDA: Initial meeting, Development Meeting, Efficacy, Safety,
- Challenging points for overseas companies in relation to the PMDA : Testing protocols, Low powered clinical study, differences from the predicate device, etc.
- Things that PMDA could require you to do in Japan: Efficacy, Safety Test, maybe clinical trial.
- Typical regulatory consulting path: Initial Study, determining the JMDN code, collection of documents, searching for predicate devices
- Why it is a good idea to visit Japan to meet your potential partners.

Our Speakers

Dr. Miyuki Shimizu - Medical Lab Partners

Dr. Shimizu brings more that 25 years of experience in the Medical Device Field and Pharma in Japan. She is the CEO of Medical Lab Partners, a leading Regulatory Consultancy and D-MAH company in Japan. Prior to starting her own company, Dr. Shimizu was a research and new business development manager at Terumo HQ, where she invented several Medical Devices. Dr. Shimizu has a Bachelor and Masters of Science degree in Chemistry from Chiba University, an MBA from Tama University, and a PhD in Medicine from Tsukuba University.
Medical Lab Partners can offer Regulatory Consulting on any class of device including IVDS, and is an expert at working with the PMDA on MD approvals.

Philip O'Neill - Parkdale Group Inc.

Philip O'Neill is the Founder and Representative Director of Parkdale Group Inc. He is a permanent resident of Japan and holds Bachelor degrees from McGill University and Concordia University, and a Master of Business Administration from McGill University in Montreal. Along with his work at Parkdale Group, he is also the Country Executive for Ortech Systems of Canada, a world leader in medical data interface systems. Since 2008, Parkdale Group has been offering Japan-based Market Entry, Marketing, and Regulatory and General management services to leading overseas companies and organizations. Parkdale Group has a vast network in Medical Device, Pharma, Academic Research, and Medical Informatics.

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