US-JAPAN
HBD EAST Think Tank Meeting 2023

Date: Thursday, December 14th, 9:30 AM-6:00 PM (JP Time)
Venue: Ariake Central Tower Hall and Conference, Hall A (4F)
Language: English & Japanese (simultaneous interpretation)

Moderator: **MIYASAKA Tomoyuki** (MHLW) & **OHASHI Moe** (PMDA)

Session A：Welcome Speeches

Time		Agenda items	Speakers and Panelists
9:30~9:35	A-1	From MHLW	**YOSHIDA Yasunori** *Deputy Director-General*, MHLW
9:35~9:40	A-2	From PMDA	**FUJIWARA Yasuhiro** *Chief Executive*, PMDA
9:40~9:45	A-3	From FDA	**Jeffrey Shuren** *Director -CDRH OFFICE,* FDA
9:45~9:50	A-4	From JFMDA	**TAKAGI Toshiaki** *Vice Chairman*, JFMDA
9:50~9:55	A-5	From AdvaMed	**Janet Trunzo** *Senior Advisor to the President, Senior Executive Vice President, Technology & Regulatory Affairs,* AdvaMed

Session B：20th Anniversary Keynote Speeches

Chair: **Neal Fearnot** (MED Institute Incorporated), **HO Mami** (Yumino Heart Clinic)

Time		Agenda items	Speakers and Panelists
10:00~10:15	B-1	HBD history	**Mitchell Krucoff** (Duke Univ.)
10:15~10:30	B-2	Achievements of HBD activities and future expectations	**SUZUKI Yuka** (Clinical Research, Innovation and Education Center, Tohoku Univ. Hospital (CRIETO))
10:30~10:35	B-3	Q & A	

Coffee Break (15 min)

Session C：Learning from HBD activity and recent update

Chair：**Aaron Lottes** (Purdue Univ.), **SAITO Shigeru** (Shonan Kamakura General Hospital)

Time		Agenda items	Speakers and Panelists
10:50~11:00	C-1	Update on HBD activities - Focusing on the last 5 years-	**MORIKAWA Hanako** (PMDA)
11:00~11:10	C-2	What we can say now based on our experience in obtaining approval in Japan and the U.S. Case 1: Japanese industry's view	**SENSHU Kazuhisa** (Terumo Corporation)
11:10~11:20	C-3	What we can say now based on our experience in obtaining approval in Japan and the U.S. Case 2: U.S. industry's view	**YASUHARA Daiki** (Medtronic Japan)
11:20~11:30	C-4	Role of Academia in HBD Activities	**YOKOI Hiroyoshi** (Fukuoka sanno Hospital)
11:30~11:35	C-5	Q & A	

Session D：Evaluating the efficacy and safety of medical devices from pre-market through post-market using RWD

Chair：**Misti Malone** (FDA), **ISHII Kensuke** (PMDA)

Time		Agenda items	Speakers and Panelists
11:40~11:50	D-1	Basic Approach in utilizing RWD for regulatory decision-making	**Misti Malone** (FDA)
11:50~12:00	D-2	Challenges in establishing RWE for pre- and post-market clinical evaluation	**NAKAMURA Masato** (Toho Univ.)
12:10~12:20	D-3	Challenges in developing devices using RWD in Japan	**KAWAHARA Kazuo** (Boston Scientific Japan)
12:20~12:40	D-4	Panel Discussion *Theme: The efficient way of collecting RWD for regulatory decision-making in pre- and post-market to accelerate device development*	**Speakers** & **Eric Chen** (Abbott Medical) **IWAISHI Chie** (Edwards Lifesciences) **Aaron Lottes** (Purdue Univ.) **SHIBA Takeshi** (PMDA)

Lunch Break (60 min)

Session E：Approaches of HBD activity to promote the development of SaMD

Chair：**Eric Chen**(Abbott Medical), **OKAZAKI Yuzuru** (PMDA)

Time		Agenda items	Speakers and Panelists
13:40~13:50	E-1	Regulation of SaMD in the U.S.	**Nicole Ibrahim** (FDA)
13:50~14:00	E-2	Regulation of SaMD in Japan	**KATO Kentaro** (PMDA)
14:00~14:10	E-3	Learning from “CureApp” :how to develop and get an approval of SaMD	**TANIGAWA Tomoyuki** (CureApp)
14:10~14:20	E-4	Points to consider in the application of AI for medical devices	**HAMAMOTO Ryuji** (National Cancer Center Research Institute)
14:20~14:40	E-5	Panel Discussion *Theme: Strategies to promote the development of SaMD from the standpoints of industry, government, and academia*	**Speakers** & **IKENO Fumiaki** (Stanford Univ.)

Session F：Approaches of HBD activity to promote the development of pediatric devices

Chair：**Nicole Gillette** (FDA), **YASUKOCHI Satoshi** (Aizawa hospital)

Time		Agenda items	Speakers and Panelists
14:45~14:55	F-1	Progress and challenges in pediatric medical device development	**FUJII Takanari** (Showa Univ. Hospital)
14:55~15:05	F-2	U.S. Regulatory initiatives to promote pediatric medical device development	**Nicole Gillette** (FDA)
15:05~15:15	F-3	The road from development to approval of pediatric medical devices and future approaches.	**NEMOTO Shintaro** (Osaka Med. Pharm. Univ.)
15:15~15:25	F-4	Utilization of RWD in pediatric medical device development	**INUZUKA Ryo** (Tokyo Univ.)
15:25~15:55	F-5	Panel Discussion *Theme: Strategies to promote the development of pediatric medical devices from the standpoints of industry, government, and academia*	**Speakers** & **Sung-Hae Kim** (Shizuoka Children’s Hospital) **AIZAWA Koichi** (PMDA) **Eric Vang** (Medtronic Cardiac Surgery)

Coffee Break (15 min)

Session G：What should be considered for global harmonization of medical device development through HBD activity ?

Chair：**Mitchell Krucoff** (Duke Univ.), **YABANA Naoyuki** (PMDA)

Time		Agenda items	Speakers and Panelists
16:10~16:20	G-1	An overview of the global situation surrounding medical devices	**IKENO Fumiaki** (Stanford Univ.)
16:20~16:30	G-2	Current situation of medical device regulations outside of Japan and the U.S.	**Katharine Stohlman** (Corvia Medical)
16:30~16:40	G-3	Comparing clinical practices or consultation processes in the US vs Japan	**Robert Thatcher** (Diaxamed, LLC)
16:40~16:50	G-4	Unique points of medical device development and advantages of global development.	**IKEDA Koji** (CRIETO)
16:50~17:00	G-5	Post-approval hurdles: Differences and strategies between Japanese and the U.S. insurance systems	**TAMURA Makoto** (Healthcare System Planning Institute (HSPI))
17:00~17:55	G-6	Panel discussion *Theme: Future direction of HBD activity*	**Speakers** & **Nicole Gillette** (FDA), **NAKAI Kiyohito** (MHLW) **Janet Trunzo** (AdvaMed), **TANAKA Shiho** (JFMDA, J&J) **IWAMOTO Shin** (MHLW)

Session H：Closing remarks　NAKAYAMA Tomonori (MHLW)

Anyone can participate in the reception party (18:30-20:00).
Venue: Ariake Central Tower Hall and Conference (3F)

Please tell us your impressions of participating in HBD East Think Tank 2023. This survey will take approximately 3 minutes to complete. Thank you in advance for your participation.

MHLW 厚生労働省 Ministry of Health, Labour and Welfare of Japan

pmda 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

医機連 一般社団法人 日本医療機器産業連合会 JFMDA The Japan Federation of Medical Devices Associations

US-JAPAN
HBD EAST Think Tank Meeting 2023

～ US-JAPAN Government-Academia-Industry Medical Device Regulatory Harmonization Conference ～

Date：2023. **12.14**（Thu）
9:30～18:00

Simultaneous interpretation available

Registration needed & Free of Charge

Venue: **Ariake Central Tower Hall and Conference**

Programme：**Please see the following page**

What is HBD???

- ✓ HBD (Harmonization By Doing) is a joint effort by Government-Academia-Industry in Japan and the US to harmonize medical device regulations in both countries through "practical activity". HBD has achieved significant results such as the rapid approval of medical devices in the cardiovascular field in both countries.
- ✓ As one of the activities of HBD, a "Think Tank" is held once a year, alternating between Japan and the US. The purpose of the Think Tank is to inform medical device development companies and the general public about HBD's latest activities.

  (Ref: https://www.pmda.go.jp/int-activities/int-harmony/hbd/0015.html)
- ✓ This year's Think Tank will be the first face-to-face meeting in Japan in four years, and since 2023 is the 20th anniversary of HBD, we have prepared a full program to review the past achievements and discuss future prospects. We look forward to your participation!

Please register via here (Deadline: 2023.11.21)

Contact: HBD East 2023 Secretariat Email: global*jfmda.gr.jp (replace * with @)

Organizers:
Ministry of Health, Labour and Welfare (MHLW)
Pharmaceuticals and Medical Devices Agency (PMDA)
Japan Federation of Medical Device Industries (JFMDA)