US-JAPAN
HBD EAST Think Tank Meeting 2023

～日米産官学による医療機器規制調和会議～

日時：2023年12月14日（木）
9:30～18:00（開場：9:00）

日米同時通訳あり

対面開催
要申込
（参加費無料）

会場：有明セントラルタワーホール&カンファレンス

プログラム：次ページ以降をご覧ください

開催の趣旨

HBD（Harmonization By Doing）とは「実践」を通して日米における医療機器規制の整合化を図ることを目的とした、日米の官・学・民による共同の活動です。これまでに国際共同治験の実施などにより、
日米両国で循環器領域の医療機器の迅速な承認に繋がる大きな成果を上げています。

HBDの活動の一つとして、年1回の「シンクタンク」を日米交互に開催しています。本シンクタンクの目的は、HBDの最新の活動内容等を医療機器開発企業や一般の方を含め広く知って頂くことです。
（参考HP：https://www.pmda.go.jp/int-activities/int-harmony/hbd/0015.html）

本年の「シンクタンク」は4年ぶりの日本での対面開催となります。2023年はHBD発足20年の記念すべき年でもあることから、これまでの成果を振り返るとともに、今後の展望を議論する充実したプログラムを準備しています。皆様奮っての御参加をお待ちしています。

こちらよりお申込みいただけます（参加登録〆切：11月21日）

お問い合わせ：HBD East 2023 事務局 Email:global*jfmda.gr.jp （*を@に置きかえてお送りください）

主催：厚生労働省、（独）医薬品医療機器総合機構、
（一社）日本医療機器産業連合会

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)

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
Language: English & Japanese (simultaneous interpretation)

Moderator: Tomoyuki Miyasaka (MHLW) & Moe Ohashi (PMDA)

		Time	Speakers and Panelists	
	Agenda items (Draft)		**US**	**JP**
Session A：Welcome Speeches (9:30~)				
A-1	From MHLW	5		Yasunori Yoshida
A-2	From PMDA	5		Yasuhiro Fujiwara
A-3	From FDA	5	Jeffrey Shuren	
A-4	From JFMDA	5		Toshiaki Takagi
A-5	From AdvaMed	5	Janet Trunzo	
Session B：20th Anniversary Keynote Speeches (10:00~)				
Chair			Neal Fearnot (MED Institute Incorporated)	Mami Ho (Yumino Heart Clinic)
B-1	HBD history	15	TBD	
B-2	Achievements of HBD activities and future expectations	15		Yuka Suzuki (Clinical Research, Innovation and Education Center, Tohoku University Hospital(CRIETO))
B-3	Q＆A	5		
Coffee Break (15min)				
Session C：Learning from HBD activity and recent update (10:50~)				
Chair			Aaron Lottes (Purdue Univ.)	TBD
C-1	Update on HBD activities - Focusing on the last 5 years-	10		Hanako Morikawa (PMDA)
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	10		Kazuhisa Senshu (Terumo Corporation)
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	10	Daiki Yasuhara (Medtronic)	
C-4	Role of Academia in HBD Activities	10		Hiroyoshi Yokoi (Fukuoka sanno Hospital)
C-5	Q＆A	5		
Session D：Evaluating the efficacy and safety of medical devices from pre-market through post-market using RWD (11:40~)				
Chair			Misti Malone (FDA)	Kensuke Ishii (PMDA)
D-1	Basic Approach in utilizing RWD for regulatory decision-making	10	Misti Malone (FDA)	

D-2	Challenges in establishing RWE for pre- and post-market clinical evaluation	10		Masato Nakamura (Toho Univ.)
D-3	Challenges in developing devices using RWD in Japan	10		Kazuo Kawahara (Boston Scientific Japan)
D-4	Panel Discussion Theme: The efficient way of collecting RWD for regulatory decision-making in pre- and post-market to accelerate device development	30	Speakers & Eric Chen (Abbott) & Chie Iwaishi (Edwards Lifesciences) & Aaron Lottes (Purdue Univ.)	Speakers & Takeshi Shiba (PMDA)
Lunch Break (60 min)				
Session E：Approaches of HBD activity to promote the development of SaMD (13:40~)				
Chair			Eric Chen (Abbott)	Yuzuru Okazaki (PMDA)
E-1	Regulation of SaMD in the U.S.	10	Nicole Ibrahim (FDA)	
E-2	Regulation of SaMD in Japan	10		Kentaro Kato (PMDA)
E-3	Learning from “CureApp” :how to develop and get an approval of SaMD	10		Tomoyuki Tanigawa (CureApp)
E-4	Points to consider in the application of AI for medical devices	10		Ryuji Hamamoto (Division of Medical AI Research and Development, National Cancer Center Research Institute)
E-5	Panel Discussion Theme: Strategies to promote the development of SaMD from the standpoints of industry, government, and academia	20	Speakers & Fumiaki Ikeno (Stanford univ.)	Speakers
Session F：Approaches of HBD activity to promote the development of pediatric devices (14:45~)				
Chair			Nicole Gillette (FDA)	Satoshi Yasukochi (Aizawa hospital)
F-1	Progress and challenges in pediatric medical device development	10		Takanari Fujii (Showa Univ.)
F-2	U.S. Regulatory initiatives to promote pediatric medical device development	10	Nicole Gillette (FDA)	
F-3	The road from development to approval of pediatric medical devices and future approaches.	10		Shintaro Nemoto (Osaka Med. Pharm. Univ.)
F-4	Utilization of RWD in pediatric medical device development	10		Ryo Inuzuka (Tokyo Univ.)
F-5	Panel Discussion Theme: Strategies to promote the development of pediatric medical devices from the standpoints of industry, government, and academia	30	Speakers & TBD	Speakers & Tohru Kobayashi (Department of Data Science, Center for Clinical Research, National Center for Child

				Health and Development) & Koichi Aizawa (PMDA)
Coffee Break (15 min)				
Session G：What should be considered for global harmonization of medical device development through HBD activity ? (16:10~)				
Chair			TBD	Naoyuki Yabana (PMDA)
G-1	An overview of the global situation surrounding medical devices	10	Fumiaki Ikeno (Stanford univ.)	
G-2	Current situation of medical device regulations outside of Japan and the U.S.	10	Kate Stohlman (Corvia Medical)	
G-3	Comparing clinical practices or consultation processes in the US vs Japan	10	Robert Thatcher (DIAXAMED)	
G-4	Unique points of medical device development and advantages of global development.	10		Koji Ikeda (Clinical Research, Innovation and Education Center, Tohoku University Hospital(CRIETO))
G-5	Post-approval hurdles: Differences and strategies between Japanese and the U.S. insurance systems	10		Makoto Tamura (Healthcare system planning institute (HSPI))
G-6	Panel discussion Theme: Future direction of HBD activity	50	Speakers & Nicole Gillette (FDA) & Janet Trunzo (AdvaMed)	Speakers & Kiyohito Nakai (MHLW) & TBD
Session H：Closing Remarks (17:55~)				
H-1	Closing remarks	5		Tomonori Nakayama (MHLW)