US-JAPAN
HBD EAST 2025 Think Tank Meeting

～日米産官学による医療機器規制調和会議～

日米
同時通訳
あり

対面開催
要申込
（参加費無料）

日時：2025年**9**月**17**日（水）
9:30～18:00（開場：9:00）

会場：**札幌コンベンションセンター**

プログラム：こちら

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について、医療機器開発企業や一般の方を含め広く知っていただくことです。
（参考HP：https://www.pmda.go.jp/int-activities/int-harmony/hbd/0015.html）

本年の「シンクタンク」では、これまでの成果を振り返るとともに、開発促進が期待される分野や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：8月31日）

お問い合わせ：HBD East 2025 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 2025 Think Tank Meeting

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

Date：2025.9.17（Wed）
9:30～18:00

Simultaneous interpretation available

In person & Registration needed (Free of Charge)

Venue: Sapporo Convention Center

Program: Please click here

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)
- ✓ We have prepared a full program to review the past achievements and discuss the areas where accelerated development is anticipated and future prospects. We look forward to your participation!

Please register via here (Deadline: 2025.8.31)

Contact: HBD East 2025 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 2025

Date: Wednesday, September 17th, 2025, 9:30 AM- 6:00 PM (JST)
Venue: Sapporo Convention Center (https://www.sora-scc.jp/eng/access.html)
Language: English & Japanese (simultaneous interpretation)

Session		Chair	Agenda items	Times	Speakers and Panelists
A	Welcome 9:30-9:55		From MHLW	5	**NOMURA Yumiko** *Director, Medical Device Evaluation Division, Ministry of Health, Labour and Welfare (MHLW)*
			From PMDA	5	**FUJIWARA Yasuhiro** *Chief Executive, Pharmaceuticals and Medical Devices Agency （PMDA）*
			From FDA	5	**TBA** *U.S. Food & Drug Administration (FDA)*
			From JFMDA	5	**MIYATA Masahiko** *Vice Chairman, The Japan Federation of Medical Devices Associations (JFMDA)*
			From AdvaMed（AMDD）	5	**Janet Trunzo** *Senior Advisor to the President, Senior Executive Vice President, Technology & Regulatory Affairs, AdvaMed*
B	Keynote lecture 9:55-10:30		Japanese initiatives to promote medical device development	15	**SUZUKI Yuka** (Clinical Research, Innovation and Education Center, Tohoku Univ. Hospital (CRIETO))
			HBD history and global lessons learned	15	**Mitchell Krucoff** (Duke Univ.)
			Q&A	5	
C	Update on HBD activities 10:35-10:45		Update on HBD activities (2020 – 2025)	10	**NAKAGAWA Makoto** (PMDA)
Break (15min)					
D	HBD activities to advance pediatric device development and access 11:00-12:10	**YASUKOCHI Satoshi** (Aizawa hospital), **Nicole Ibrahim** (FDA)	HBD for Children - Achievements and future directions	10	**SASAGAWA Kaoru** (PMDA)
			Considerations in Japanese academia in advancing pediatric medical device development: Insight from Japan's Agency for Medical Research and Development	10	**FUJII Takanari** (SHOWA Medical Univ. Hospital)
			Japanese regulatory initiatives to promote pediatric/orphan medical device access	10	**ANDO Mariko** (MHLW)
			What else is needed to advance pediatric medical device development? Industry perspective	10	**Dali Alarian** (Renata Medical)
			Panel discussion: Breaking barriers: Driving cross-sector collaboration and increased global access	30	**Speakers** & **Sung-Hae Kim** (Shizuoka Children's Hospital) **SUZUKI Yuka** (CRIETO) **Eric Chen** (Abbott Medical) **Nicole Gillette** (FDA) **TAKAHASHI Sara** (MHLW)
Lunch Break (60 min)					
E	HBD activities to advance smart development of SaMD 13:10-14:20	**IKENO Fumiaki** (Stanford Univ.),	Regulatory updates: Japan	10	**KOIKE Kazuhisa** (PMDA)
			Regulatory updates: US	10	**Ken Cavanaugh** (FDA)
			Initiatives to support the expansion of Japanese medical devices into overseas markets: Japanese ministry	10	**TAKAYAMA Masumi** (Ministry of Economy, Trade and Industry)

Session		Chair	Agenda items	Times	Speakers and Panelists
		KOIKE Kazuhisa (PMDA)	perspective		
			Considerations in international development of digital health technologies	10	**TADA Tomohiro** (AI Medical Service Inc.)
			Panel discussion: Global strategies to accelerate SaMD development: perspectives from industry, academia, and government	30	**Speakers &** **IKEDA Koji** (CRIETO) **OTAKE Masanori** (GE HealthCare Japan)
F	Challenges and solutions when building multi-national registries 14:25-15:35	**IWAMOTO Shin** (PMDA), **Kenneth Cavanaugh** (FDA)	The current situation and future direction of utilization of real-world clinical evidence for regulatory decision-making	10	**SHIBA Takeshi** (PMDA)
			Experiences with regulatory use of registry data: Industry perspective	10	**IWAISHI Chie** (Edwards Lifesciences)
			Consideration and future opportunities identified through the utilization of real-world evidence	10	**Aaron Lottes** (Purdue Univ.)
			Deciding whether a registry should go global: Japanese academic perspective	10	**NAKAMURA Masato** (Toho Univ.)
			Panel Discussion: Opportunities for further global alignment of real-world evidence collection and application	30	**Speakers &** **YOKOI Hiroyoshi** (Fukuoka Sanno Hospital) **Misti Malone** (FDA) **YASUHARA Daiki** (Medtronic JAPAN)
Break (15min)					
G	Shaping forward-looking collaboration among stakeholders for more efficient global medical device development 15:50-17:10	**Mitchell Krucoff** (Duke Univ.), **YABANA Naoyuki** (PMDA)	Addressing key bottlenecks in global medical device development: challenges and strategic solutions	10	**SENSHU Kazuhisa** (Terumo Corporation)
			Lessons from success: Rethinking collaboration among stakeholders in medical device innovation	10	**IKEDA Koji** (CRIETO)
			Initiatives to accelerate medical device access: US regulatory perspective	10	**Kenneth Cavanaugh** (FDA)
			Advancing medical device development through multinational collaboration	10	**TBA**
			Panel discussion: Envisioning global collaboration in medical device development - a 10-year outlook from industry, academia, and government	40	**Speakers** & **IKENO Fumiaki** (Stanford Univ.) **MORIKAWA Satoshi** (Boston Scientific Japan) **NAKAI Kiyohito** (PMDA) **Health Sciences Authority** **EU regulator**
H	Closing remarks			5	**YABANA Naoyuki** (PMDA)