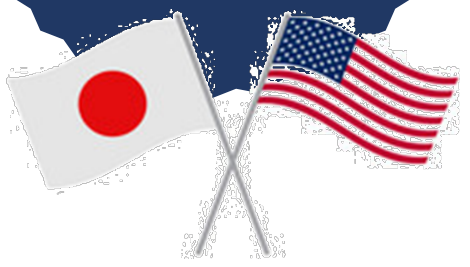
US-JAPAN
HBD EAST 2025 Think Tank Meeting

～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17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

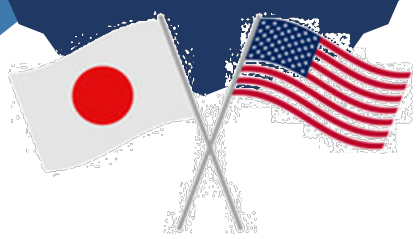
US-JAPAN
HBD EAST 2025 Think Tank Meeting

～ 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: 2025.8.17)

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)

Agenda for HBD East 2025 Think Tank Meeting (Draft)

Session		Agenda items
A	Welcome	
B	Keynote lecture	Japanese initiatives to promote medical device development
		HBD history and global lessons learned
C	Update on HBD activities	Update on HBD activities (2020 – 2025)
D	HBD activities to advance pediatric device development and access	HBD for Children - Achievements and future directions
		Considerations in Japanese academia in advancing pediatric medical device development: Insight from Japan's Agency for Medical Research and Development
		Japanese regulatory initiatives to promote pediatric/orphan medical device access
		What else is needed to advance pediatric medical device development? Industry perspective
		Panel discussion: Breaking barriers: Driving cross-sector collaboration and increased global access
E	HBD activities to advance smart development of SaMD	Regulatory updates: Japan
		Regulatory updates: US
		Initiatives to support the expansion of Japanese medical devices into overseas markets: Japanese ministry perspective
		Considerations in international development of digital health technologies
		Panel discussion: Global strategies to accelerate SaMD development: perspectives from industry, academia, and government
F	Challenges and solutions when building multi-national registries	The current situation and future direction of utilization of real-world clinical evidence for regulatory decision-making
		Experiences with regulatory use of registry data: Industry perspective
		Consideration and future opportunities identified through the utilization of real-world evidence
		Deciding whether a registry should go global: Japanese academic perspective
		Panel Discussion: Opportunities for further global alignment of real-world evidence collection and application
G	Shaping forward-looking collaboration among stakeholders for more efficient global medical device development	Addressing key bottlenecks in global medical device development: challenges and strategic solutions
		Lessons from success: Rethinking collaboration among stakeholders in medical device innovation
		Initiatives to accelerate medical device access: US regulatory perspective
		Advancing medical device development through multinational collaboration
		Panel discussion: Envisioning global collaboration in medical device development - a 10-year outlook from industry, academia, and government
H	Closing remarks	