

IMDRF Stakeholder Forum

Sapporo Convention Center, Conference Hall, Japan
Tuesday, 16 September 2025

Registration 9:00 - 9:30 am	
Opening Remarks 9:30 to 9:35 am	
Title	Welcome
Speakers	Naoyuki YASUDA, Chair, IMDRF2025; Associate Executive Director for International Programs, PMDA
Session 1: IMDRF Regulatory Updates 9:35 am – 12:55 pm	
Speakers	Australia, TGA (10min) Brazil, ANVISA (10min) Canada, Health Canada (10min) China, NMPA (10min) EU, European Commission (10min) Japan, MHLW (10min) Russia, Ministry of Health (10min) Q&A for Previous Speakers (15min)
Coffee Break 11:00 - 11:20 am	
Speakers	Singapore, HSA (10min) South Korea, MFDS (10min) Switzerland, Swissmedic, Swiss Agency for Therapeutic Products (10min) United Kingdom, MHRA (10min) United States of America, U.S. FDA (10min) Argentina (Official Observer), ANMAT (10min) Saudi Arabia (Official Observer), SFDA (10min) (10min) World Health Organization (Official Observer), WHO (10min) Q&A for Previous Speakers (15min)
Lunch Break 12:55 - 1:55 pm	
Session 2: WG Updates 1:55 – 2:30 pm	
Speaker	WGs Update, IMDRF Secretariat, PMDA (20min) Q&A (15min)
Session 3: RHI Updates 2:30 – 3:10 pm	
Speakers	AMDF (10min) APEC (10min) PAHO (10min) Q&A for Previous Speakers (10min)
Coffee Break 3:10 - 3:30 pm	

Session 4: Affiliate Member Updates		3:30 – 4:20 pm
Speakers	EDA, Egypt (10min) DINAVISA, Paraguay (10min) Drug Safety Center, Ministry of Health, Oman (10min) MDA, Malaysia (10min) Q&A for Previous Speakers (10min)	
Session 5: Implementation and Challenges of UDI		4:20 to 5:20 pm
Panelists	TGA ANVISA MHLW Japan SFDA Medtronic BD	
Moderators	DKMA, Biomerieux	
Closing Remarks		5:20 to 5:30 pm
Speaker	Naoyuki YASUDA, Chair, IMDRF2025; Associate Executive Director for International Programs, PMDA	