IMDRF / Industry Joint Workshop

Modernizing Conformity Assessment Through Innovative Processes

Sapporo, Japan
Monday, September 15, 2025
9:30 am – 5:20 pm

This workshop topic aims to illuminate the challenges and opportunities with conformity assessment throughout product life cycle. Through the course of this workshop, speakers will share conformity assessment practices to build trust and predictability. The goal of the workshop is to explore opportunities for IMDRF to identify unmet needs and drive convergence in medical device and IVD assessment practices.

Session Time	**Registration** 9:00-9:30 am
Opening Remarks (9:30–9:50 am)	
Session Speaker	Welcome address by IMDRF Chair PMDA
Session Speaker	Welcome address by IMDRF Chair MHLW
Session Speaker	Welcome address by Industry DITTA, GMTA
Session1 Scene Setting: Conformity Assessment for MD/IVD (9:50-11:10 am)	
Title Speaker	**Keynote Speech: Conformity Assessment for Medical Devices and IVDs based on IMDRF /GHTF principles** HSA
Title Speaker	**Conformity Assessment in Practice: Industry Challenges and Opportunities** Industry
Title Panellists Moderators	**Panel Discussion** HSA MFDS WHO Affiliate Member Industry US FDA Industry
Break (11:10-11:30 am)	

Session 2: Classification approaches to foster convergence: Mapping challenges and considerations (11:30 pm – 12:45 pm)	
Title Speaker	**Navigating Divergent Device Classifications: Industry Experience Across Jurisdictions** Industry
Title Speakers	**How differences in classification can impact evidence requirements and the conformity assessment** ANVISA Affiliate Member
Title Panellists Moderators	**Panel Discussion** ANVISA NMPA Roszdravnadzor Affiliate Member Industry Health Canada Industry
Lunch Break (12:45 -1:45 pm)	
Session 3: Improving Post-Market Surveillance (1:45-3:15 pm)	
Title Speaker	**Challenges in Current Post-Market Surveillance** Industry
Title Speaker	**Leveraging Digital Technologies for Smarter Post-Market Surveillance** Swissmedic
Title Speaker	**Harmonizing International Regulatory Approaches for Efficient Post-Market Conformity** TGA
Title Panellists	**Panel Discussion** Swissmedic TGA Affiliate Member RHI Industry

Moderator	European Commission Industry
Break (3:15-3:35 pm)	
Session4: Emerging best practices in evidence development: Leveraging advances in real-world evidence (RWE) and other innovative evidence types to fill data gaps created by classification differences (3:35-5:20 pm)	
Title Speaker	**Regulatory Initiatives on RWE: Advancing the Use of RWE in Conformity Assessment** MHRA
Title Speaker	**Experience of utilizing RWE in pre- and post-market** Industry
Title Speakers	**Examples of gaps in clinical evidence** Industry
Title Panellists Moderators	**Panel discussion** PMDA SFDA Industry MHRA Industry
Session Speaker	Closing Remarks (5:15-5:20 pm) IMDRF Chair
Networking Reception 5:30 PM -	