IMDRF / Industry Joint Workshop

Modernizing Conformity Assessment Through Innovative Processes

Sapporo Convention Center, Conference Hall
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.

Registration 8:30-9:30 am	
Opening Remarks	**9:30 – 9:50 am**
Speaker	Welcome address by IMDRF Chair • Naoyuki Yasuda, Associate Executive Director for International Programs, PMDA
Speaker	Welcome address • Yumiko Nomura, Director, Medical Device Evaluation Division Pharmaceutical Safety Bureau. Ministry of Health, Labour and Welfare
Speaker	Welcome address by Industry • Yuji Yanagida-JIRA, DITTA • Koji Sekiguchi- JFMDA, GMTA
Session1 Scene Setting: Conformity Assessment for MD/IVD	**9:50 – 11:10 am**
Title Description Speaker	**Keynote Speech: Conformity Assessment for Medical Devices and IVDs based on IMDRF /GHTF principles** This keynote will provide a regulatory overview of conformity assessment for MDs/IVDs based on internationally recognized guidance documents and standards. It will highlight key principles, current expectations, and the role of regulators in supporting globally aligned, evidence-based regulatory pathways. • HSA (20min)
Title Description Speaker	**Conformity Assessment in Practice: Industry Challenges and Opportunities** This presentation introduces industry experiences with conformity assessment in practice, highlighting challenges and opportunities encountered across classification approaches, post-market surveillance, and the use of real-world evidence. Case examples will illustrate how evolving regulatory expectations are shaping practical implementation and global alignment efforts. • Shimadzu (10min) • Boston Scientific (10min)

Title	**Panel Discussion** (40 min)
Panellists	• HSA • MFDS • WHO • DIGEMAPS • Shimadzu • Boston Scientific
Moderators	• US FDA • Philips
Coffee Break 11:10-11:30 am	
Session 2: Classification approaches to foster convergence: Mapping challenges and considerations	**11:30 am – 12:45 pm**
Title	**How differences in classification can impact evidence requirements and the conformity assessment**
Description	The presentation will examine how differences in device classification across jurisdictions can lead to varying evidence requirements and conformity assessment pathways. It will also discuss how such inconsistencies may pose challenges to the effective implementation of reliance mechanisms in global regulatory practices.
Speaker	• ANVISA (15min)
Title	**Navigating Divergent Device Classifications: Industry Experience Across Jurisdictions**
Description	The presentations provide Industry experiences for one device may be classified differently across jurisdictions and how industry works to facilitate market authorization in such situations
Speakers	• Roche (10min) • AITRICS (10min)
Title	**Panel Discussion** (40min)
Panellists	• ANVISA • NMPA • Roszdravnadzor • CPPS • AITRICS • Roche
Moderators	• Health Canada • Medtech Canada

Lunch Break 12:45 -1:45 pm	
Session 3: Improving Post-Market Surveillance	**1:45 – 3:15 pm**
Title Description Speaker	**Challenges in Current Post-Market Surveillance** While GHTF/IMDRF documents provide a foundation for harmonized post-market surveillance (PMS), manufacturers often face significant gaps between this global guidance and national regulatory requirements. This presentation will explore how inconsistencies in interpretation, implementation, and local expectations create challenges for effective and efficient PMS across jurisdictions. • Abbott (10min)
Title Description Speaker	**Harmonizing International Regulatory Approaches for Efficient Post-Market Conformity** This presentation will highlight TGA's actions in post-market surveillance. • TGA (10min)
Title Description Speaker	**Leveraging Digital Technologies and Innovative Approaches for Post-Market Surveillance: An Industry Example/Case Study** This presentation will share a case study featuring one manufacturer's use of digital technology for proactive post-market surveillance. It will highlight learnings regarding tool deployment, use of the tool for managing data and identifying trends, and practical insights regarding opportunities and challenges when considering innovative tools for post-market surveillance. • BD (10min)
Title Description Speaker	**Leveraging Digital Technologies for Smarter Post-Market Surveillance** This presentation will showcase Swissmedic's initiatives to leverage digital technologies for more proactive PMS. It will also share lessons learned and future plans to strengthen regulatory capabilities through digital transformation. • Swissmedic, Swiss Agency for Therapeutic Products (10min)
Title Panellists Moderators	**Panel Discussion** (50min) • Swissmedic, Swiss Agency for Therapeutic Products • TGA • CDSCO • Abbott • BD • MTAA • European Commission • GE Healthcare

Coffee 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 – 5:15 pm**
Title Description Speaker	**Regulatory Initiatives on RWE: Advancing the Use of RWE in Conformity Assessment** This presentation will provide an overview of real-world evidence (RWE), including key definitions and regulatory frameworks relevant to medical devices and IVDs. It will also introduce regulatory initiatives to promote the use of RWE in the conformity assessment of MDs/IVDs. • MHRA (20min)
Title Description Speaker	**Experience of utilizing RWE in pre- and post-market** This presentation will share practical experiences of applying real-world evidence (RWE) to support regulatory decision-making in both pre-market evaluation and post-market surveillance of medical devices. • J&J (15min)
Title Description Speaker	**Examples of gaps in clinical evidence** This presentation will highlight common gaps in clinical evidence identified during conformity assessment processes and discuss their impact on regulatory outcomes. • Cook Medical (15min)
Title Panellists Moderators	**Panel discussion** (50min) • PMDA • SFDA • J&J • Cook Medical • MHRA • MedTech Europe
Closing Remarks	**5:15-5:20 pm**
Speaker	• Naoyuki Yasuda, IMDRF Chair, Associate Executive Director for International Programs, PMDA
Networking Reception at Hall C 5:30 pm -	