Joint IMDRF/Industry Workshop on Strategic Plan/Reliance

Monday, 10 March 2025

9:30 am – 4:50 pm

The Part I Strategic Plan 2026-2030 session aims to address the development of IMDRF's next medium-term plan. This session will focus on evaluating the results of the Strategic Plan Survey, exploring the challenges of IMDRF members in implementing IMDRF guidance documents, and examining training and capacity-building initiatives to enhance regulatory reliance and convergence. Sub-themes include regulator and industry feedback on the Strategic Plan and expected outcomes, the status and challenges of consistent IMDRF document implementation, and the development of training models to support effective training and capacity building for implementation. Establishing a clear and actionable strategic framework is essential to addressing emerging regulatory needs and promoting global convergence and harmonization.

The Part II Challenges in expanding Reliance session will highlight Reliance as a strategic priority and regulatory approach that enables faster patient access to innovative medical devices while optimizing resource allocation. At the IMDRF-25 joint workshop, we discussed the definition of reliance, shared case studies from various jurisdictions, and explored its benefits and potential next steps. Building on those insights, this session will focus on identifying and addressing the challenges involved in expanding reliance frameworks. We aim to delve into issues such as regulatory alignment, implementation barriers, and cross-jurisdictional collaboration, using the findings from the previous workshop as a foundation for the discussion.

Session Time	**Registration** 9:00-9:30 AM
Opening Remarks (9:30 - 9:50 am)	
Session Speaker	Welcome speech MHLW
Session Speaker	Welcome address by PMDA PMDA
Session Speaker	Welcome address by Industry Industry - GMTA Industry - DITTA
I. IMDRF Strategic Plan 2026 – 2030	
Session 1 Scene Setting (9:50 – 11:05 am)	
Title Speaker	**Strategic Plan Survey Result** IMDRF Secretariat
Title Speakers	**Strategic Plan Survey from Industry perspective** Industry 1 (GMTA) Industry 2 (DITTA)
Title Panellists	**Panel Discussion** IMDRF Secretariat OO 1 (Swissmedic) AM 1 (NAFDAC) RHI 1 (GHWP) Industry 2 (DITTA)

Moderators	MC 1 (Health Canada) Industry 1 (GMTA)
Break (11:05-11:25 AM)	
Session 2: Progress and challenges in Implementation of IMDRF guidance documents (11:25 am– 12:25 pm)	
Title Speakers	**Status of implementation of IMDRF guidance documents and issues** MC 2 (NMPA) Industry 3 IEC expert
Title Panellists Moderators	**Panel Discussion** MC 2 (NMPA) MC 3 (MFDS) OO 2 (WHO) AM 2 (CECMED) AM 3 (SAHPRA) Industry 3 (KMDIA) IEC expert MC 4 (HSA) Industry 4
Lunch Break (12:25-1:40 PM)	
Session 3: Education models for Training and Capacity Building at Current IMDRF initiatives, RHI experience (1:40 – 2:30 pm)	
Title Speaker	**RHI presentation on the current effort of Training and Capacity Building initiatives** RHI 2 (APEC)
Title Panellists Moderator	**Panel Discussion** MC 5 (ANVISA) MC 6 (PMDA) OO 3 (SFDA) AM 4 (EFDA) RHI 2 (APEC) MC 7 (DKMA) Industry 5
Break (2:30-2:50 PM)	
II. Challenges in expanding Reliance (2:50 – 4:40 pm)	
Title Speakers	Overview of “White paper on Reliance at IMDRF-25” Industry 6 Industry 7
Title Speakers	Sharing jurisdictional case studies and challenges in expanding Reliance MC 8 (MHRA) MC 9 (TGA)

	OO 4 (ANMAT) Industry 8 Industry 9
Title Panellists Moderators	**Panel discussion** MC 8 (MHRA) OO 4 (ANMAT) AM 5 (COFEPRIS) RHI 4 (AMDF) Industry 6 Industry 7 Industry 8 MC 9 (TGA) Industry 9
Closing Remarks	IMDRF Chair 4:40-4:50 PM
Networking Reception	5:00 PM -