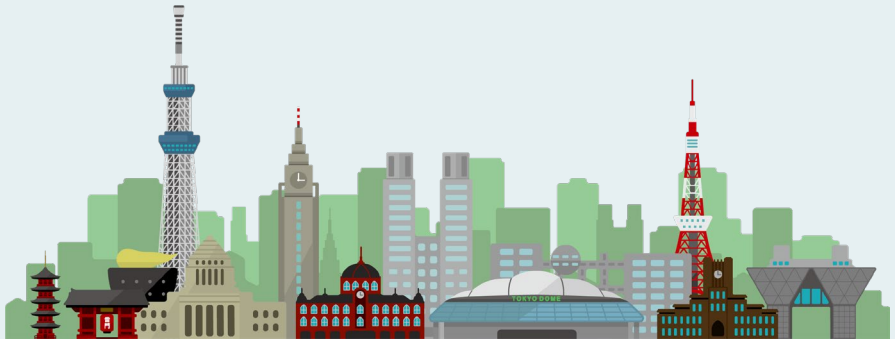
IMDRF International Medical Device Regulators Forum



Strategic Plan Survey
Industry Perspective

Maurizio Andreano, DITTA

IMDRF-Industry Joint Workshop - March 10, 2025

Responses Collected by DITTA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

The united global industry voice for **diagnostic imaging, radiation therapy, healthcare IT, electromedical equipment and radiopharmaceuticals,** representing more than 600 medical technology manufacturers incl. SMEs, committed to improving health care and patient outcomes.

2018: Recognized Non State Actor in Official Relations with WHO
2016: MoU with the World Bank
2015: NGO Status with WHO
2014: Official Liaison with AHWP /GHWP

DITTA - Expectations from IMDRF's Activities

Comprehensive strategy along with a clear implementation process:

1) **Regulatory Framework**: Establish a clear and coherent regulatory framework
2) **Categorization of Documents**: Categorize IMDRF guidance documents into "Foundational", "Growth" and "Accelerated" and link to the regulatory framework
3) **Implementation**: Adoption into national regulations
4) **Training and Capacity Building**: Develop and deliver training programs for effective application
5) **Expand Reliance**: Foster collaboration among regulatory authorities and continue journey towards MD Single Review Program (MDSRP)

Pre-specified Answers:

- ❑ Timely Updates of IMDRF documents
- ❑ Detailed Explanations of issued IMDRF documents
- ❑ Adoption of new activities

DITTA - Benefits of Engaging with IMDRF

1) **Platform**: Providing industry an opportunity to share perspectives and contribute to international harmonization efforts
2) **Global Trends**: Obtain information on international regulatory trends and progress made towards harmonization and convergence
3) **Patient Access**: Help ensure equitable market access of current and innovative devices
4) **Regulatory Frameworks**: Contribute to shaping a harmonized regulatory framework that support continuous innovation

Pre-specified Answers:

- ❑ Participation in WG Activities
- ❑ Communication with Regulatory Authorities
- ❑ Early response to regulations based on IMDRF documents

DITTA – Activities for IMDRF to Focus on

1) **Regulatory Harmonization**: Continue promoting regulatory harmonization effectively based on a comprehensive strategy with a clear implementation process
2) **Reliance**: Develop dedicated documents and trainings to support the application of reliance
3) **Electronic Submission**: Foster a common submission format across countries
4) **Change Management Practices**: Advance practices to ensure streamlined Post-Market Surveillance (PMS) and vigilance requirements
5) **Capacity Building**: Engage in capacity building efforts with a standard curriculum aligning different training initiatives of IMDRF documents ensuring consistent interpretation

DITTA – Update of Foundational IMDRF/GHTF Documents

1) Continue to develop the GHTF Regulatory Model *(GHTF/AHWG-GRM/N1R13:2011)* as framework linking relevant guidance documents
2) Use the Quality Management System Working Group to update GHTF Study Group documents*
3) Maintain focus on updating core foundational documents**

* 1) Implementation of risk management principles and activities within a Quality Management System: GHTF/SG3/N15R8:2005
2) Design Control Guidance for Medical Device Manufacturers: GHTF/SG3/N99-10:2004
3) Quality management system - Medical Devices - Guidance on corrective action and preventive action and related QMS processes: GHTF/SG3/N18:2010
4) Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers: GHTF/SG3/N17:2008

** 1) Essential Principles: IMDRF/GRRP WG/N47: 2024
2) Principles of Medical Device Classification: GHTF/SG1/N77:2012
3) Principles of Conformity Assessment for Medical Devices: GHTF/SG1/N40: 2006
4) Definition of Terms “Medical Device” and “IVD”: GHTF/SG1/N29: 2005

DITTA – Innovative Topics for IMDRF to Address in the Future

1) New and innovative premarket pathways such as predetermined change control plan (PCCP) or expedited/ special pathways for innovative technologies
2) How to determine "product sameness" in support of reliance activities

DITTA – Topics for future IMDRF-industry joint workshops

- Examples of reliance in practice
- Predetermined change control plan (PCCP)
- QMS inspection in pre-market review conformity assessment
- Digital / e-Labeling
- Strengthening Conformity Assessments using the Standards Liaison Program
- Exploring Medical Device Single Review Program (MDSRP), including eStar / RPS
- Challenges for Clinical Evaluation and Evidence
- Capacity building best practices and establishment of IMDRF accredited training schemes

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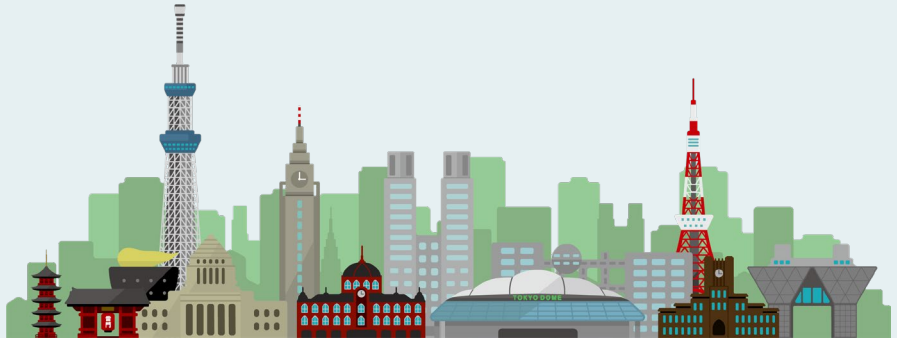

Thank you/Questions