HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

29th IMDRF 2026

Global regulatory trends for medical technologies

Global Medical Technology Alliance (GMTA)

Diana Kanecka

Director International Affairs
MedTech Europe

Global Diagnostic Imaging, Healthcare ICT, And Radiation Therapy Trade Association (DITTA)

Diane Wurzburger

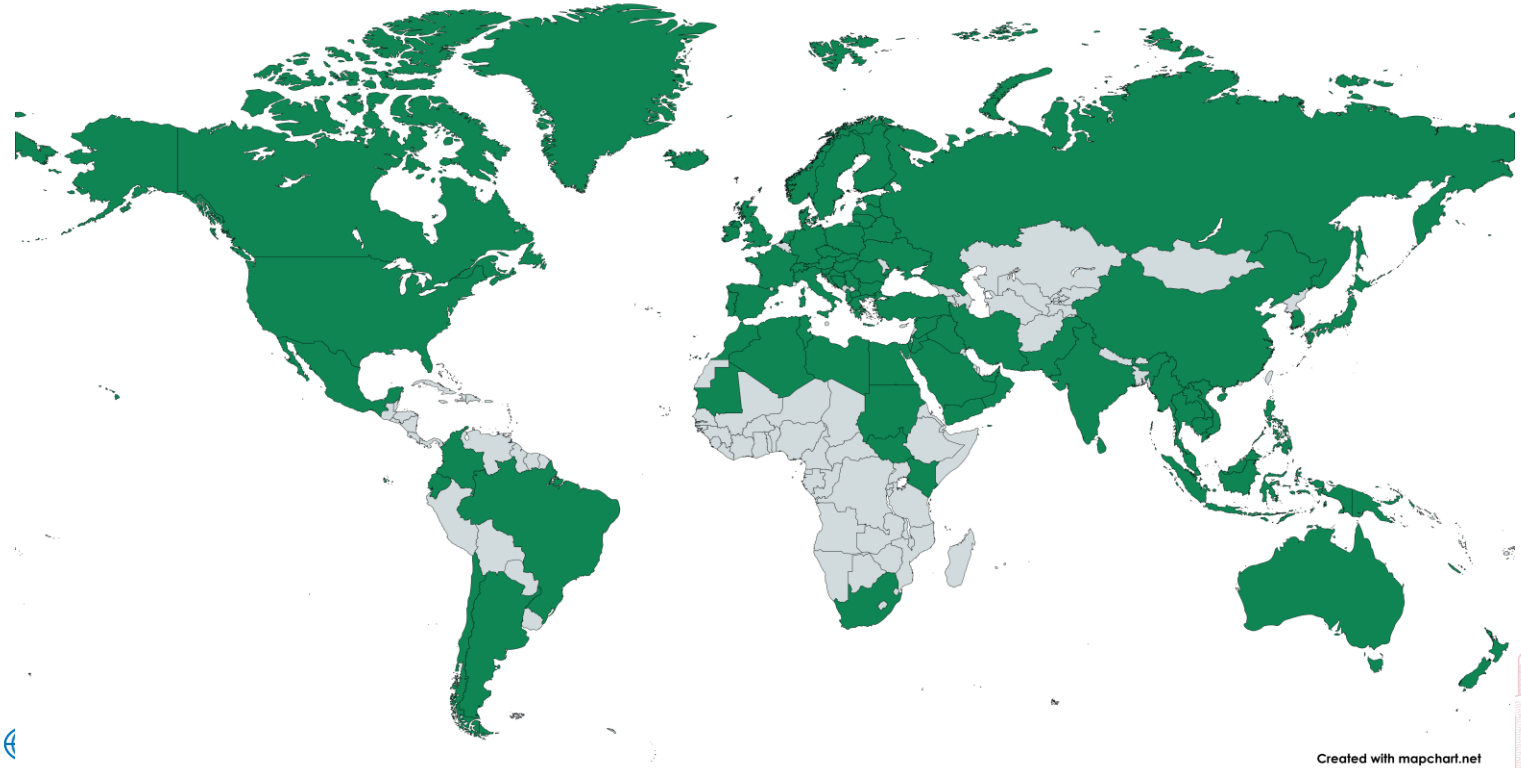
VP Regulatory, Quality, and Global Policy

DITTA GLOBAL PRESENCE

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

2018: DITTA as a recognized non state actor in official relations with WHO
2016: DITTA MoU with the World Bank
2014: DITTA has official liaison with (AHWP) GHWP

GMTA Global Presence: Over 30 member associations



DITTA and GMTA express support and appreciation for:

- **IMDRF efforts towards regulatory convergence and reliance**
- **IMDRF WGs with industry participants (DITTA: QMS, SaMD, AI/ML, Clinical Trials, IVDs, Cybersecurity, etc.)**
- **Channeling feedback from industry through public consultations on IMDRF documents**
- **A collaborative relationship between IMDRF and Industry Group**

Major Trends Shaping Device Regulation

- Modernizing regulatory systems
- Lifecycle based regulation
- Regulation of emerging technologies

Implementation of IMDRF guidance is essential to avoid fragmentation and support global innovation.

Advancing Convergence through IMDRF

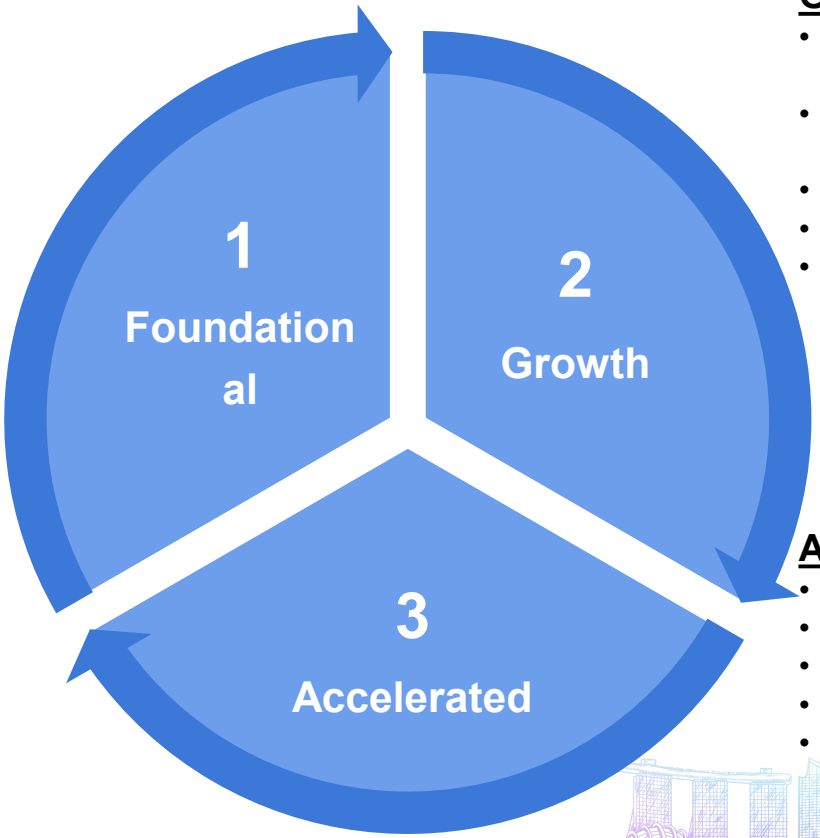
- IMDRF has developed a substantial body of guidance covering key principles of medical device and IVD regulation

- **Identifying foundational IMDRF documents and capacity building are essential to:**
  - Support more consistent global implementation
  - Help identifying priority guidance for adoption
  - Further strengthen regulatory convergence

Navigating IMDRF guidance: Fit for need

Foundational Examples:

- Essential Principles of Safety and Performance
- Definition of Terms MD & IVD
- Principles of MD Classification
- Quality System
- Principles for Labeling MD & IVD
- Terminologies for Categorized AE Reporting
- Content of Field Safety Notices
- Principles of Conformity Assessment
- Optimizing Standards for Regulatory Use
- Non IVD Clinical Evidence Definitions and Concepts
- Playbook for Medical Device Regulatory Reliance Programs



Growth Examples:

- Clinical Performance Studies for IVDs
- Post Market Clinical Follow Up Studies
- Non IVD Clinical Evaluation
- Clinical Evidence for IVDs
- MDSAP

Accelerated Examples:

- UDI
- Software as a Medical Device
- Machine Learning
- Cybersecurity
- PCCP

Regulatory alignment – It's a journey & we're on it together

Thank You!