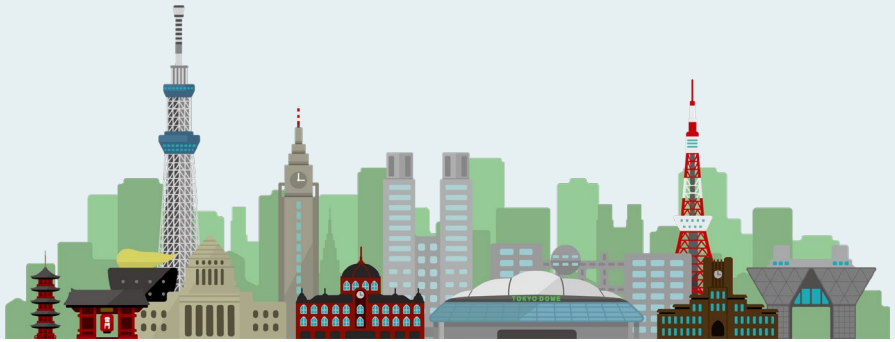
IMDRF International Medical Device Regulators Forum



Strategic Plan Survey
Industry Perspective - GMTA

Nicole Taylor Smith, GMTA
IMDRF-Industry Joint Workshop - March 10, 2025

Global Medical Technology Alliance
Innovating for a Healthier World

Responses Collected by the Global Medical Technology Alliance (GMTA)

- GTMA member associations are **national or regional medical technology associations.**
- GMTA represents companies that produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments.
- GMTA represents companies that **produce nearly 85 percent of the health care technology** purchased and utilized annually around the world. Our companies range from the largest to the smallest innovators and bring medical technology.

GMTA Global Medical Technology Alliance

GMTA – Input for formulating the next Strategic Plan

1. *As an important user of IMDRF documents, what do you want from IMDRF's activities?*

1) **Training and Capacity Building**: Training, practical guidance, and clear expectations of IMDRF documents to ensure regulators and stakeholders can effectively adopt and align with IMDRF principles
2) **Timely updates on IMDRF documents** and activities, including opportunities for comment and participation
3) **Adoption of new activities** with an eye to the future
4) **Industry engagement**

Pre-specified Answers:

☒ Timely Updates of IMDRF documents

☒ Detailed Explanations of issued IMDRF documents

☒ Adoption of new activities

☒ Other (Please propose specific approach)

GMTA - Benefits of Engaging with IMDRF

2. *What do you think are the benefits of engaging with IMDRF?*

1) **Building trust** with regulators and showing industry is solution oriented.
2) **Promoting communication** with regulators to **foster harmonization, regulatory reliance, and alignment** across IMDRF member jurisdictions.
3) **Staying informed of global trends and progress** toward harmonization and regulatory convergence.
4) **Participation in IMDRF WG activities**
5) **Early response to regulations based on IMDRF documents**

Pre-specified Answers:

- ☒ Participation in WG Activities
- ☒ Communication with Regulatory Authorities
- ☒ Early response to regulations based on IMDRF documents
- ☒ Other (Please propose specific approach)

GMTA – Activities for IMDRF to Focus on

3. *What do you think are activities that IMDRF should focus on more, or that are also or alternatively handled by other regulatory initiatives?*

- IMDRF should prioritize **initiatives that promote global regulatory efficiency, harmonization, and convergence.** Including:
  - ✓ Work to establish a **common submission format**, such as eSTAR, and
  - ✓ **Fostering regulatory reliance** to optimize both regulator and industry resources.

- Key focus areas should also include:
  - ✓ **Advancing change management practices**,
  - ✓ **Ensuring streamlined post-market surveillance (PMS)** and **vigilance requirements**,
  - ✓ Supporting the adoption of **electronic Instructions for Use (eIFU)**, and
  - ✓ **Harmonizing pathways for regulatory processes across member jurisdictions**.

GMTA – Activities for IMDRF to Focus on

3. *What do you think are activities that IMDRF should focus on more, or that are also or alternatively handled by other regulatory initiatives?*

- IMDRF should be involved in:
  - ✓ **Capacity building** and **training** to ensure aligned interpretation and adoption of IMDRF documents.
  - ✓ Other harmonization initiatives are also involved in training train to IMDRF documents and concepts – we would like IMDRF to help **ensure these efforts are coordinated to ensure consistency and accuracy.**

- IMDRF should **encourage its members to integrate IMDRF documents into their local frameworks** to ensure consistency and alignment with global best practices. This may include step-by-step instructions.

GMTA – Update of Foundational IMDRF/GHTF Documents

4. *If there are any foundational IMDRF/GHTF documents that you think IMDRF should especially continue to update, please list them in detail.*

- **Quality Management System (QMS):** Focus on revitalizing the QMS Working Group (WG) to update the GHTF Study Group 3 documents, including:
  - SG3/N15R8 Risk Management
  - SG3/N99-10:2004 Process Validation
  - SG3/N18:2010 Corrective and Preventive Action (CAPA)
  - SG3/N17:2008 Control of Products and Services Obtained from Suppliers
- **Post-Market Surveillance (PMS):** Continue efforts to refine and update documents related to PMS and vigilance activities, e.g. N65 Post-Market Clinical Follow-Up Studies
- **N52 Principles of Labeling:** Should be updated to further advancements in the adoption and harmonization of eIFU standards and include acceptance of digital labels
- **Adverse Event (AE) Reporting:** Revisit and improve multiple documents related to AE reporting for consistency and global applicability
- **GHTF/FD: 99-7** Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative, June 1999
- **N51:** Optimizing Standards for Regulatory Use
- **N55:** Clinical Evidence-Key Definitions and Concepts
- **N56:** Clinical Evaluation
- **N57:** Clinical Investigation

GMTA – Innovative Topics for IMDRF to Address in the Future

5. *If there are any innovative topics that you think IMDRF should tackle in the future, please list them in detail.*

- **Innovative or new types of pathways for submission**, such as including PCCP, or an expedited or special pathway for innovative devices
- **Single review program/MDSRP**- building on the single audit program and regulated product submission (RPS)/eSTAR
- **Digital health and AI**, exploring concepts such as single audit for AI products
- **Device classification**, especially for AI and other innovative products

GMTA – Topics for future IMDRF-industry joint workshops

6. *Are there any topics you would like to see in future IMDRF-industry joint workshops?*

- Continuation of **reliance and implementation**, including the **playbook**
- **Health industry consultations with authorities throughout the life cycle of the device** (e.g. U.S. and Japan)
- **Predetermined change control protocols** (PCCPs)
- **Digital/e-labeling**
- Regulated product submission or eSTAR, including **learnings from eSTAR shared pilots**

GMTA – Commitment to Supporting IMDRF

7. Additional Comments

- **GMTA is committed to IMDRF's work** and appreciates the opportunity to provide comments on this Strategic Plan.
- We, along with DITTA, are **ready and willing to provide technical and other expertise and work with the Management Committee and Affiliate Members.**
- GMTA also **strongly supports IMDRF's efforts to continue to expand affiliate membership.**

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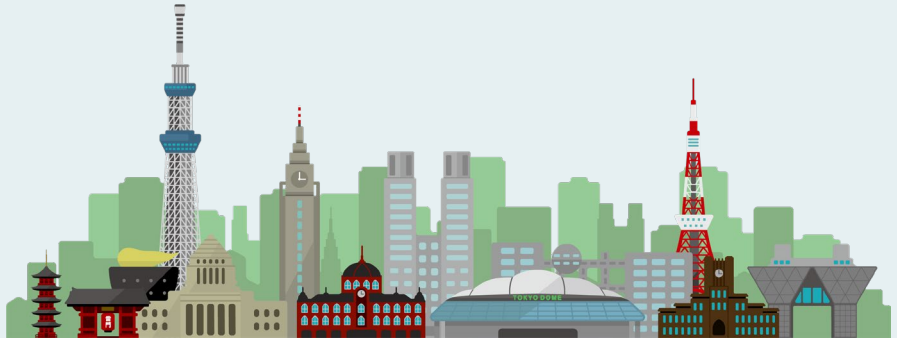

Thank you!

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