IMDRF
International Medical Device Regulators Forum

2024 26th Session
Seattle, Washington

Joint Workshop

between

IMDRF and DITTA and GMTA

Developing a Medical Device Regulatory System

16 September 2024

White Paper

Developing a Medical Device Regulatory System

This White Paper summarizes the discussions and observations arising from the International Medical Device Regulators Forum (IMDRF) 26th Session Joint IMDRF-DITTA and GMTA Workshop on "Developing a Medical Device Regulatory System." The workshop was chaired by the United States under its role as the IMDRF Chair for 2024.

Scene Setting- Different Paths to Developing a Regulatory System

The workshop began with the World Health Organization (WHO) sharing the tools and guidelines they have published to support jurisdictions in the development of medical device regulatory systems. These tools include the Global Model Regulatory Framework (GMRF), Good Regulatory Practices, and Good Reliance Practices documents. The GMRF is a roadmap to build an effective and efficient regulatory framework and aligns with IMDRF foundational guidance.

Panelists discussed different paths to developing a regulatory system for medical devices, noting that a strong regulatory system is a critical component of well-functioning healthcare delivery. Jurisdictions began regulating medical devices from a variety of starting points, many originating from the foundations of pharmaceutical regulatory frameworks. Regardless of the starting point, regulators face similar challenges and questions.

The discussion demonstrated that regulatory systems vary across jurisdictions. For example, some jurisdictions use third parties for certain regulatory activities, some use reference jurisdictions, and different regulators may focus on different aspects of pre- and post-market regulation. Both industry and regulators emphasized the importance of harmonization and the use of standards where possible to support an efficient use of resources by all parties.

Panelists spoke to the impact of IMDRF on all stakeholders, noting that no single stakeholder has enough resources and expertise themselves. All must work together and partner to get safe and effective devices to patients in a timely manner.

Observations:

- WHO has published a number of documents supportive of developing a medical device regulatory system.
- Many aspects to developing a regulatory system are common across jurisdictions. However, there is also variation (e.g. "one size doesn't fit all").
- All stakeholders benefit from leveraging one another's knowledge and expertise.

Session 1 – Enabling Conditions for Effective Regulation of Medical Devices

This session began with an overview of the enabling conditions as articulated in WHO's GMRF. Panelists then discussed their experiences in and observations of developing regulatory systems, highlighting how the enabling conditions impacted their own journey.

Regulators noted the need for highly trained staff and the challenge of resource constraints in implementing efficient and effective regulatory systems. IMDRF documents and training were cited as important tools in accelerating the development of qualified regulatory staff and supporting efficient use of resources (e.g., no need to "reinvent the wheel").

Regulators acknowledged the challenges in obtaining the appropriate legal foundation for regulation of medical devices and the need for tools (e.g., regulation and guidance) that are easily adaptable in the ever-evolving medical device industry (e.g., regulation of and support of innovation for devices with artificial intelligence). Speakers also highlighted transition periods as being particularly hard to navigate.

Panelists spoke about certain types of partnerships in the medical device ecosystem that play an important role in supporting effective medical device regulation:

- IMDRF brings stakeholders together at a global level;
- Regional harmonization initiatives build capacity to implement IMDRF technical documents and engagement within their regions;
- Regulators work with one another on specific cases when more tailored approaches are called for; and
- Industry identifies opportunities for harmonization and supports capacity building efforts.

Observations:

- The GMRF outlines the enabling conditions for effective regulation of medical devices.
- Resource constraints and the need for qualified staff are common challenges in developing a medical device regulatory system.
- Each stakeholder plays an important role in supporting effective regulation of medical devices. Relationships at global (e.g., IMDRF), regional (e.g., Regional Harmonization Initiatives), and bilateral (e.g., regulator to regulator) levels as well as with different stakeholder types (e.g., industry and regulators) support harmonization and convergence of approaches.

Session 2 – Stepwise Approach to Regulating Medical Devices

During this session, speakers presented on different steps to developing a regulatory system for medical devices. Topics included reliance and recognition, publication of laws and regulations, and basic and expanded level controls in pre and postmarket settings.

Speakers from regulatory authorities shared insights from the development of the regulatory framework in their own jurisdiction to illustrate how different ideas and considerations might be operationalized. Speakers also identified relevant IMDRF guidance documents that serve as references and tools at each step of developing a regulatory system.

Medical device regulatory authorities are diverse in age, size, and experience. IMDRF plays an important role in bringing these diverse regulatory authorities and other stakeholders (e.g., industry, regional harmonization initiatives) together to learn from one another and work towards harmonization.

Observations:

- Setting up a medical device regulatory system takes significant time and resources.
- By publishing harmonized technical documents on topics ranging from key definitions to enforcement to regulation of innovative products (e.g., software, cybersecurity), IMDRF plays a critical role in supporting jurisdictions at all different stages of developing medical device regulatory systems.

Session 3 – Next Steps

The Next Steps session summarized the discussions throughout the workshop. Panelists acknowledged the stepwise nature of developing a regulatory system and the need for patience as regulators work towards implementation of different aspects of a medical device regulatory framework.

Panelists discussed IMDRF's role in supporting jurisdictions through the process of developing a medical device regulatory system. In addition to publication of harmonized technical documents, the panelists emphasized IMDRF's role to bring stakeholders together to exchange ideas and support one another.

Observations:

- IMDRF plays a critical role in bringing stakeholders together to share experiences and build trust.
- External engagement is a common element in the journey to regulatory maturity
- Future work for IMDRF to support development of effective, efficient regulatory systems could include:
    - Continue to publish globally harmonized documents on topics of international importance;
    - Provide training and support to regulators implementing IMDRF technical documents; and
    - Identify opportunities to partner with stakeholders across the medical device ecosystem in the advancement of regulatory convergence and reliance.