Date	Document	Project Nr.
12/3/25	IMDRF Strategic Plan	

Company	Line number	Clause/ Subclause	Paragraph Figure/ Table	Type of comment (General/ Technical/Editorial)	COMMENTS	Proposed change	Notes
GMTA and DITTA	48-50	1.2		General	Globalized production and emerging technologies are not challenges per se; rather, they underscore the need for greater regulatory convergence. These trends increase interdependence among markets and accelerate innovation, making harmonized approaches essential to avoid duplication and delays. Similarly, global health problems—such as pandemics—highlight the urgency of coordinated regulatory frameworks to ensure timely, equitable access to safe medical technologies for patients worldwide.	The IMDRF addresses the common public health needs for regulatory ~~challenges to~~ convergence due to the globalization of medical device production, ~~and~~ the emergence of new technologies, and global health challenges. IMDRF provides the structure where the strategic decisions and operational mandates are made by public health-missioned medical device regulators, based on appropriate, equitable and transparent input from stakeholders.	
GMTA and DITTA	59-60	1.3		Technical	This section could be more specific on what may be considered “best practices.” This could include best practices in regulatory processes and/or advancing innovations in regulatory science. Recommend explicitly including supporting the advancement of regulatory science.	Suggest the following addition to the bullet “Promote open discussion and the sharing of best practices and advances in regulatory science, including use of technology for internal processes, among regulatory authorities responsible for medical device regulation.”	
GMTA and DITTA	97-8	2.0	2.1	Technical	While it is true that COVID-19 catalysed reliance implementation, it is important for IMDRF to recognize that reliance is a tool for all medical devices and IVDs. It is not only for emergency use or “critical medical products.” Rather, reliance should be applied as part of everyday regulatory processes to accelerate all products to patients since timely access to all medical products and diagnosis is critical.	After line 96: As regulators have learned more about reliance, they are embracing this tool for more than critical medical products or emergency use. Reliance has become a foundational element of their regulatory process. After line 98: IMDRF responded by continuing to support convergence and by supporting the development of the Reliance Playbook; a stepwise approach for how to operationalize reliance through the total product lifecycle while maintaining jurisdictional autonomy.	

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GMTA and DITTA	99-102	2.0	2.2	Technical	Industry is grateful to IMDRF for taking a leadership role in the development of an MD/IVD-specific guidance. This is necessary to support regulators across the world. Reliance provides flexibility in that regulators may choose which type of reliance is appropriate for them. While some regulators, such as those with complex, mature regulatory frameworks, pursue extensive mapping of regulation with the reference agency, this is not the path for all regulators. For implementation of reliance, the reference agency's regulation needs to be as stringent or more stringent than the relying jurisdiction. As some regulators are creating first-time regulation of MD/IVDs or have little regulation, this extensive mapping between reference agency and the relying agency does not apply. To ensure reliance continues to be characterized with the flexibility it offers and ensure regulators are represented, we recommend the suggested changes.	Depending on the level of regulation in the relying agency, reliance may require extensive regulatory alignment and requirement mapping. However, this is dependent on the level and complexity of the relying agency. Transparency in decision-making processes that IMDRF actively fostered through working group (WG) collaboration, workshops at IMDRF meetings and IMDRF trainings. It has also assisted with reliance implementation in multiple agencies.	
GMTA and DITTA	109-11	2.0	2.3	Technical	We agree that COVID-19 spurred a shift in the elements outlined in the original text. However, to ensure a broad perspective, we recommend edits as outlined in the next column.	The pandemic also spurred a shift toward remote inspections, ~~and~~ remote and decentralized clinical trials/investigations, acceptance of global clinical trial data and real-world evidence, reliance implementation and greater use of ~~greater reliance on~~ digital health technologies. ~~and broader acceptance of RWE~~	

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GMTA and DITTA	83-85	2.1		Technical	IMDRF members operate in different regulatory contexts and levels of maturity, but they share the goal of providing timely access to safe and effective Medical Devices and IVDs. Not all innovations require new or product-specific regulation. In many cases, existing laws, frameworks, and regulations can be interpreted and applied to new technologies. Because guidance will always lag innovation, it is essential that IMDRF promote regulatory agility and science so that regulators can use existing tools where appropriate and react quickly when new guidance is needed. We therefore suggest that the Strategic Plan emphasize IMDRF's role in supporting an agile, risk-based, regulatory framework that can be applied across jurisdictions with different levels of regulatory maturity, particularly at a time when many members are undertaking reform or first-time regulation.	At the same time, IMDRF has seen a significant increase in reform as well as first time regulation from its members. This provides a pivotal moment where the development of risk-based, resource appropriate harmonized approaches are is possible since many IMDRF members are undergoing regulatory reform and the advancements in technology may requires new procedures to be developed.	
GMTA and DITTA	156-7	3.0	3.1	General	We commend IMDRF for their global leadership and member inclusion achievements. We also understand that with such rapid growth comes the need to rethink approaches to ensure all members feel heard, engaged, and valued. To this end, industry stands ready to assist IMDRF, via supporting capacity building, vendor days, sharing key learning and exchanges, and pilots with the entire IMDRF membership.	NA	

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GMTA and DITTA	183-5	3.0	3.3	Technical	We agree a transparent and well-defined regulatory process helps ensure timely access to safe and effective MD/IVDs. We recommend adding “risk-based.” IMDRF is home to 47 regulators – all that differ significantly in size, maturity and experience. IMDRF may apply international best practices, so they are relevant and achievable by its members. Some members have limited resources to oversee MD and IVDs. Therefore, it is essential for IMDRF to design regulatory best practices that are risk- based. Doing so will help strengthen oversight in a sustainable way.	Fostering a transparent, well-defined, risk-based, regulatory process to demonstrate safety and effectiveness could significantly speed up the total time taken for safe and priority medical device innovations to reach patients	
GMTA and DITTA	194-195 274	3.3 4.3			International consensus standards foster global convergence and are designed to facilitate the development of technical requirements. We recommend that IMDRF explicitly recognise the role of these standards when setting priorities under Focus Area 3 and Priority Activity 3. In particular, the existence of, and/or planned development of, relevant international consensus standards should be considered alongside regulatory needs and resources before embarking on new IMDRF technical guidance. Where this is not taken into account, there is a risk of duplicative or divergent guidance that diminishes the role of standards in the regulatory process and creates unnecessary opportunities for deviation among regulators.	We suggest that the Strategic Plan: (i) highlight IMDRF’s role in reinforcing the use of international consensus standards as tools to achieve safety and performance, and (ii) clarify that topic selection for new IMDRF technical documents will take into account both regulatory needs and the availability or planned development of international consensus standards.	
GMTA and DITTA	189-193	3.3			The proposed change emphasizes the practical application of international standards and guidance documents as instruments for achieving safety and performance for medical devices. This wording reflects the role of IMDRF to promote actionable mechanisms for regulatory convergence.	This includes playing an active role in ensuring that international standards and guidance documents continue to be effective tools used to ~~in~~ conform~~ing~~ to essential principles for safety and performance for medical devices.	

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GMTA and DITTA	215-217 290-296	3.4 4.5	Text under "Expanding engagement with stakeholders" and Priority Activity 5	Technical	Please define "new stakeholders" more clearly and clarify that decision-making authority remains with IMDRF regulators. While we support broadening engagement to address cross-cutting issues and emerging technologies, the current wording of "blurring of boundaries between various sectors" and "new stakeholders with shared interests or intersections between regulatory responsibilities" is vague and could be read as expanding IMDRF's remit beyond medical devices and IVDs, or as moving towards co-governance with non-regulatory actors. We suggest that other stakeholders participate as consulted experts/observers (presenting, commenting, joining workshops), not as co-governors.	Please clarify that while IMDRF will broaden engagement with stakeholders, decision-making authority remains with IMDRF regulators.	
GMTA and DITTA	238	3.5			We strongly support the inclusion of Priority Activity 8 on enhancing IMDRF trainings. Effective, well-targeted training is essential to ensure that IMDRF documents are not only published but also practically applied and implemented consistently across jurisdictions with different levels of regulatory maturity. The proposed change emphasizes the importance of training for facilitating practical application of IMDRF documents as instruments.	Priority Activity 8: Enhance IMDRF trainings <u>to promote consistent implementation of IMDRF documents across jurisdictions.</u>	

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GMTA and DITTA	237-238	3.5	Text under “Supporting IMDRF members and stakeholders in their implementation of IMDRF documents and principles”	Technical	We strongly support IMDRF’s goal of supporting the implementation of IMDRF documents and principles by its members. The proposed priorities of developing a list of foundational IMDRF documents and enhancing IMDRF training will be highly beneficial in advancing this goal. To further strengthen this initiative, we recommend that IMDRF consider offering more hands-on, interactive support to affiliate members and other interested regulators as they adapt and integrate IMDRF guidance into their own frameworks. For example, IMDRF could explore formats such as implementation-focused Q&A sessions or virtual “office hours” where regulators can seek advice on operationalizing particular IMDRF documents, discuss practical challenges and request clarification on the intent of guidance in different regulatory contexts. Such interactive mechanisms would encourage practical engagement and knowledge-sharing among jurisdictions, while respecting national sovereignty by supporting jurisdiction-led implementation rather than prescribing specific regulatory models. By providing this targeted support, IMDRF can further advance the goal of achieving consistent implementation worldwide.		

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GMTA and DITTA	259-61	4.2		Technical	We welcome the plan to convert GHTF documents into updated IMDRF documents and recommend prioritising those related to adverse event (AE) reporting. A single, convergent IMDRF AE reporting framework would prevent further fragmentation that occurs when regulators amend or only partially adopt GHTF texts. We encourage IMDRF to build on the strengths of the existing GHTF AE guidance (clear definitions, decision criteria, exclusions and timelines), while modernising it as needed to remain fit-for-purpose and feasible for SMEs. Any move towards expanded trend or periodic reporting should be based on evidence that it improves patient safety and informed by consultation with stakeholders, to ensure that additional reporting does not impose disproportionate workload without clear benefit.	IMDRF will convert and consolidate GHTF documents (e.g. definition, PMS, risk classification) that still serve as the foundation of medical device regulation, into updated IMDRF documents, and ensure that these documents represent current best practices and that they can be adopted by a wide range of regulatory maturities while supporting patient safety. This conversion will ensure that foundational principles are aligned with current needs, supporting consistent international practices	
GMTA and DITTA	271-3	4.3		Technical	We recommend adding the suggested text because IMDRF is a leader when it comes to innovative technologies and practices. IMDRF is helping lead MD/IVD specific implementation of reliance for example. IMDRF is also creating appropriate involvement and engagement in Standards Developing Organizations.	IMDRF will continue to publish technical documents on innovative technologies and practices through a transparent and inclusive process	
GMTA and DITTA		4.6		General	Where possible, industry appreciates the opportunity to participate in various Working Groups. Where groups are not open to industry participation, multiple commenting opportunities and updates are appreciated.	Include additional options for feedback to IMDRF processes and documents.	

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GMTA and DITTA	328-330	4.7		General	We applaud IMDRF for maintaining a focus on foundational best practices and helping all members to implement them. We fully support this effort. Industry is willing to support identification of existing foundational documents. Additionally, we can provide suggestions for implementation in a staged approach. We frequently offer this support to individual jurisdictions looking at first-time regulation or reform and have received positive feedback.	NA	
GMTA and DITTA	251	4.0			Change to match point 4.5.	Together with the Industry Group, develop a proposal to further enhance stakeholder engagement.	

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GMTA and DITTA	258-268	4.2 (Convert GHTF documents to updated IMDRF documents)		Technical	We welcome the commitment to convert GHTF documents to updated IMDRF documents and to ensure that they reflect current needs. GHTF documents remain foundational for many jurisdictions, particularly those in the process of establishing or strengthening their regulatory systems, and they are widely used as a basis for reliance. To that end, we would like to emphasize the importance of genuinely modernizing these documents (e.g. for PMS) rather than simply rebranding them, and of aligning them with “current best practice” while remaining usable for jurisdictions at different levels of regulatory maturity. To avoid disruption to jurisdictions that rely heavily on GHTF documents, we recommend that IMDRF: (1) establish transparent prioritization for which GHTF documents will be revised first; (2) engage stakeholders early (including regulators from different regions and maturity levels, and the IMDRF Industry Group) in defining “current best practice,” and (3) consider providing crosswalks or transition guidance to support jurisdictions in updating their frameworks in a stepwise manner. IMDRF Regulators may also want to consider making documents machine readable, such as those related to adverse events. Industry stands ready to support		

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GMTA and DITTA	321	4.7			We strongly support the proposal to identify and maintain a set of IMDRF "foundational documents" that underpin regulatory systems and can be adopted or referenced by jurisdictions at different levels of maturity. We suggest that the Strategic Plan clarify that IMDRF will define criteria for selecting these documents, periodically review and update them to ensure guidance is current and provide practical support for fellow jurisdictions to model and follow. The IMDRF Industry group stands ready to assist in identifying which existing documents are most critical, highlighting gaps or outdated material, and providing industry perspective on how foundational documents can best support convergence, reliance, and implementation in both established and emerging regulatory frameworks.	IMDRF will work with its members and stakeholders (e.g., IMDRF Industry Group), to develop, update and publish a list of foundational documents to support navigation of IMDRF documents and prioritization of implementation by regulators, including by jurisdictions at different levels of regulatory maturity.	

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GMTA and DITTA	329 and after	5.0		Technical	We welcome the inclusion of a Progress Evaluation section and recommend that it be further strengthened to better reflect progress toward convergence and reliance. To provide clearer accountability and to demonstrate the value of IMDRF's work to members and stakeholders, we suggest that IMDRF develop a small set of simple, measurable indicators that track both outputs (e.g. number and scope of documents and trainings delivered) and outcomes (e.g. uptake and implementation of foundational documents, use of reliance involving IMDRF/GHTF principles, and stakeholder feedback on the usefulness of IMDRF outputs). We also note that previous implementation reporting appeared overly focused on procedural "yes/no" measures; more outcome-oriented indicators would better capture real-world progress and impact.		
GMTA and DITTA	158-159, 245	3.1 ; 4.1		Technical	We support the Focus Area 3.1 Modernize IMDRF governance to support sustainable, transparent growth and operations. IMDRF's membership is rapidly growing because of the creation of the affiliate membership category. The expansion of the membership is critical to driving consistent and efficient global regulatory harmonization. However, this growth creates new challenges and opportunities for IMDRF's structure and organization. Given the importance of the work in Activity 4.1, it is important to be transparent and inclusive in the process. Additional information about which IMDRF members will be in the IMDRF Governance Subcommittee would be helpful.	Please clarify which IMDRF MC members will be members of the governance subcommittee and how external input will be incorporated in the process.	