

Status of Implementation of IMDRF Guidance Documents and Issues - Industry Perspectives

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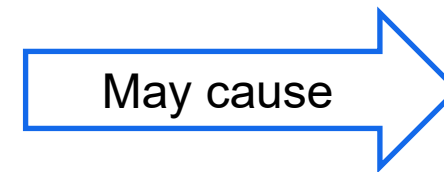
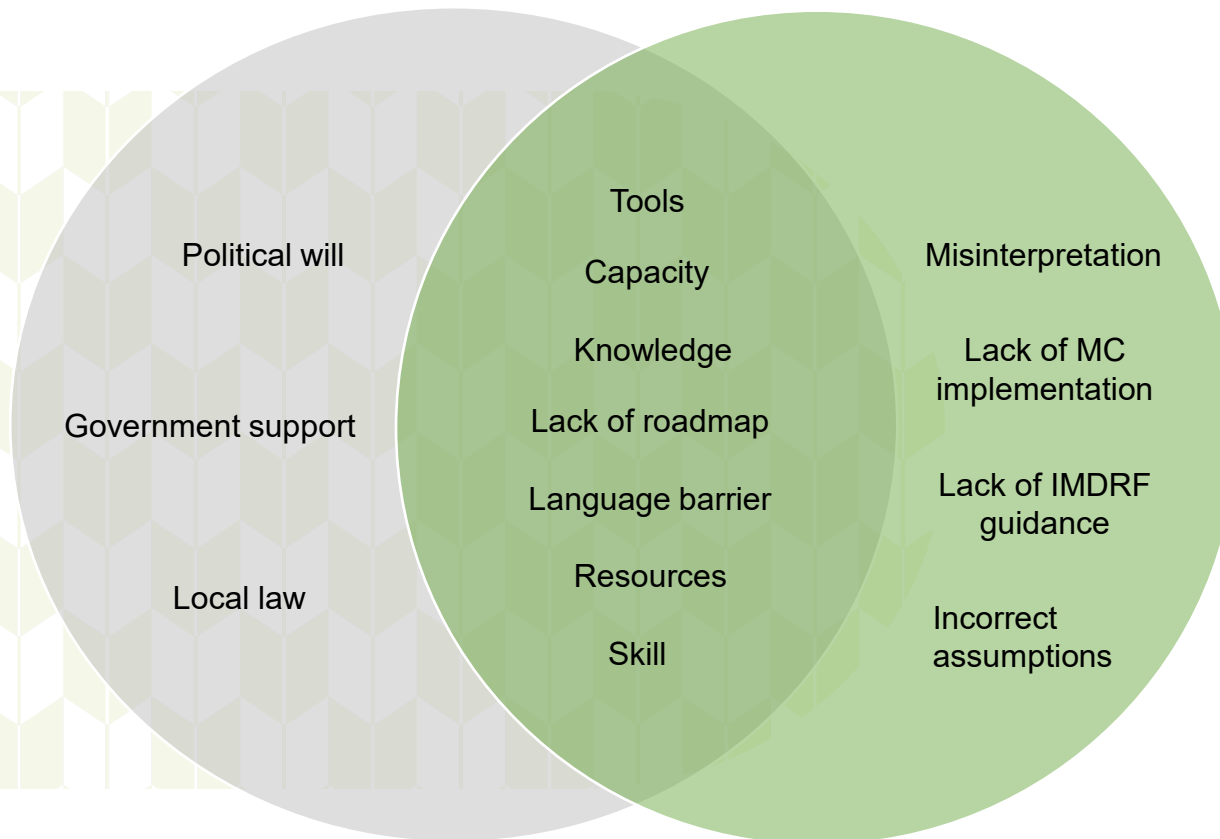
Overview

- Challenges with implementation
- Navigating IMDRF documents
- Industry's feedback on opportunities
- Recommendations

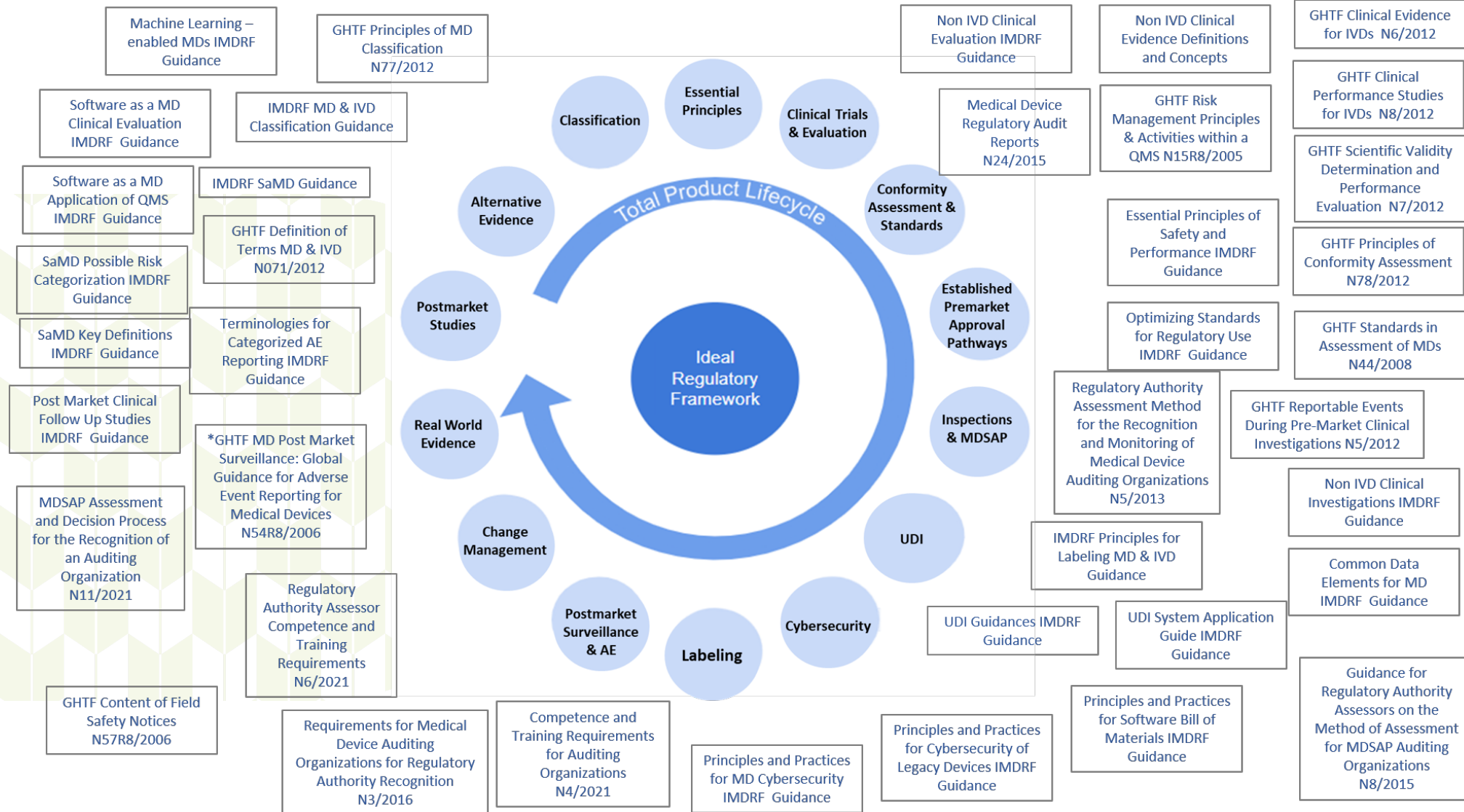




Challenges Impacting the Adoption of IMDRF Guidance



- Complexity
- Redundancy
- Delay

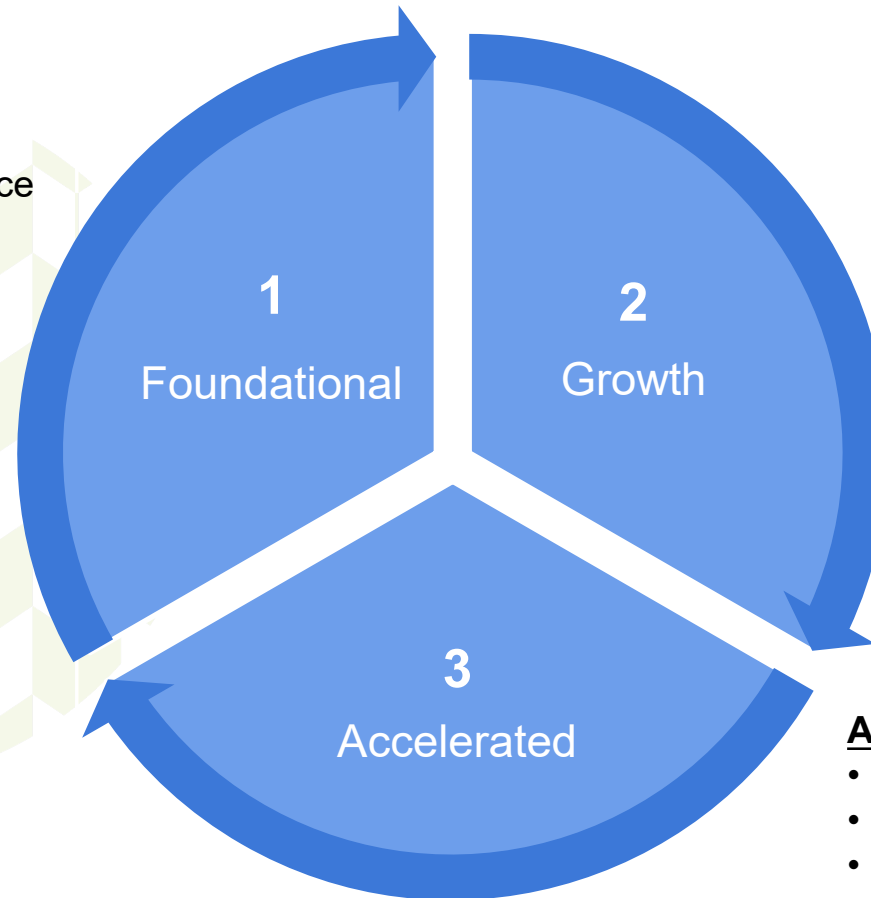




Navigating IMDRF Documents: Fit for Maturity

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



Growth Examples:

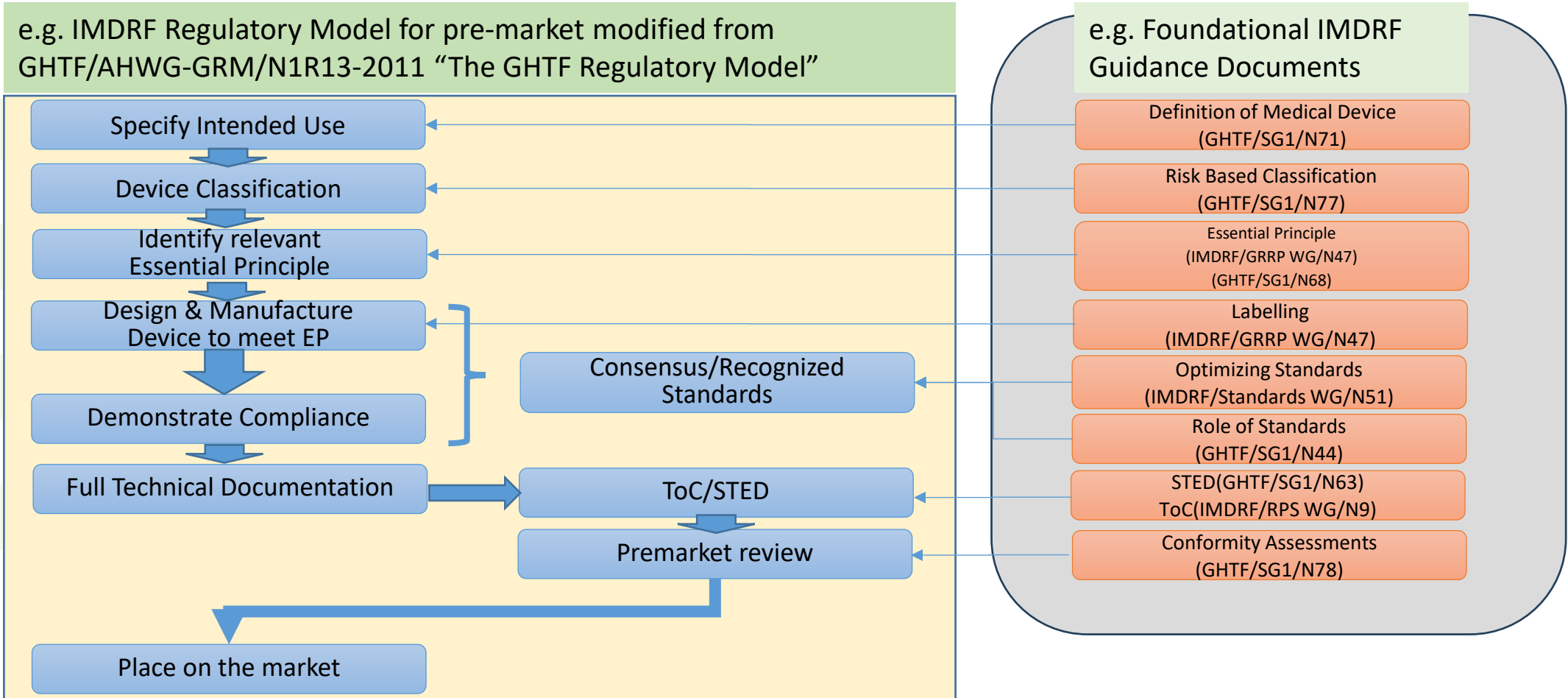
- Clinical Performance Studies for IVDs
- Post Market Clinical Follow Up Studies
- Non IVD Clinical Evaluation
- Clinical Evidence for IVDs
- MDSAP

Accelerated Examples:

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



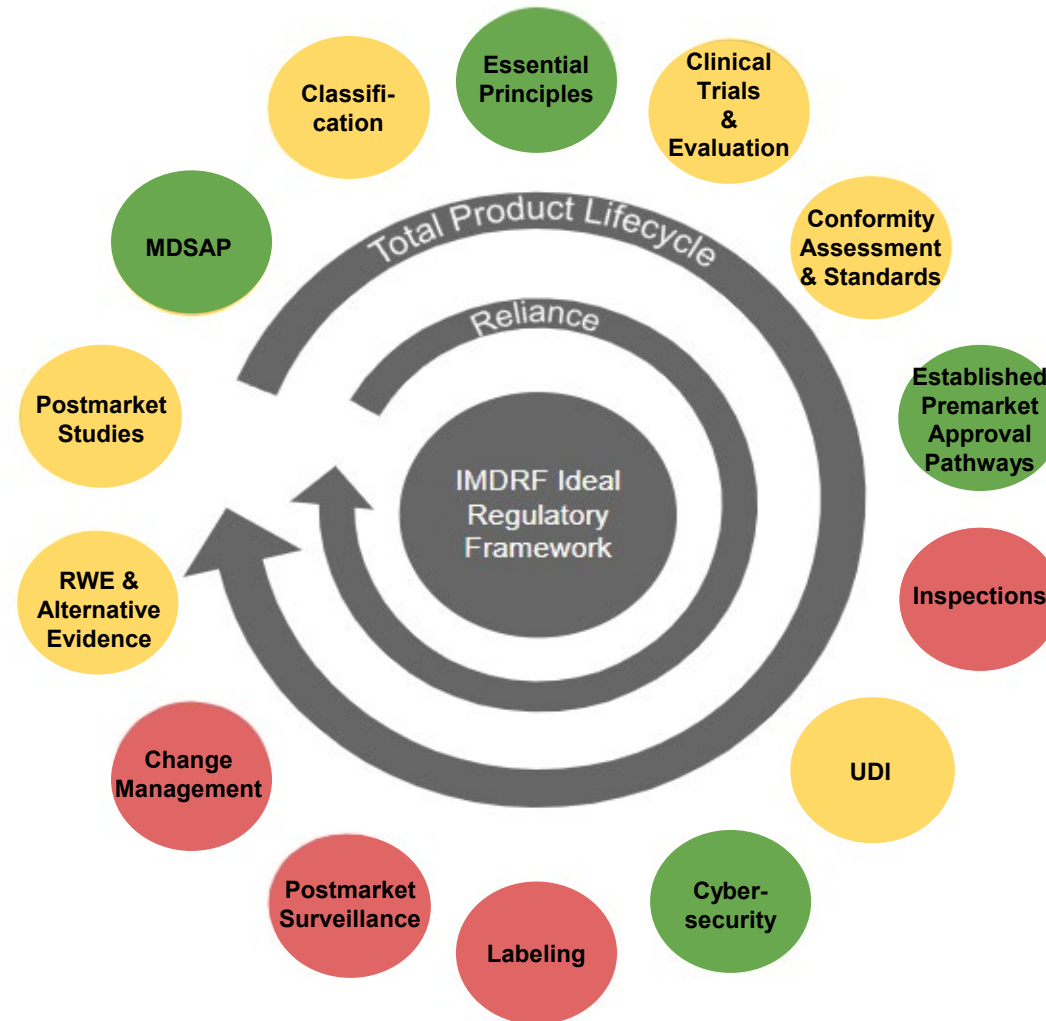
Example of Mapping based on Fit for Maturity





Areas of Opportunity

-  **Going Well** Consistent implementation where adopted
-  **Opportunity** Progress but opportunity to expand consistent adoption
-  **Focus Area** More opportunity to drive consistent adoption or develop guidance





Recommendations

- Continue to leverage stakeholder engagement opportunities:
 - Feedback from industry
 - Increase affiliate membership
 - Training and capacity building
- Deploy training and capacity building to help implementation of IMDRF documents and ensure consistent interpretation :
 - Consider translation of guidance where helpful
 - Develop an implementation roadmap and tailor to maturity
 - Transparency in implementation of IMDRF documents



Recommendations (Cont.)

- Prioritize efforts to expand convergence :
 - Inspections
 - Labeling
 - Postmarket surveillance
 - Change management
 - **Reliance across total product lifecycle**



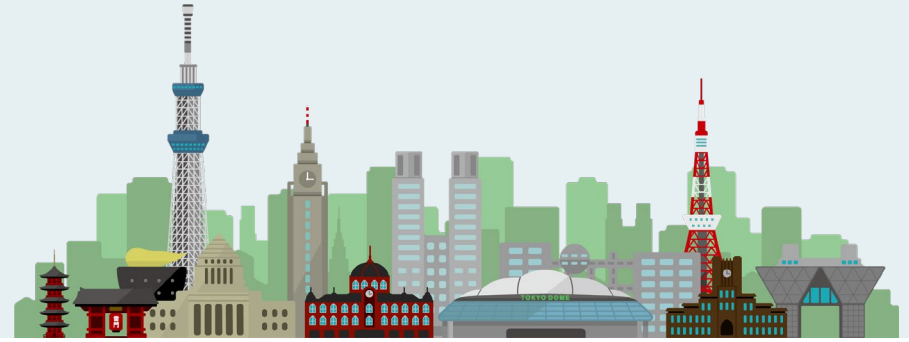
Recommendations (Cont.)

- Promote implementation of ‘Reliance’ using IMDRF Regulatory Model with Foundational IMDRF Guidance Documents
 - Fit for Maturity





IMDRF International Medical Device
Regulators Forum



Thank you/Questions
