IMDRF International Medical Device Regulators Forum

Conformity Assessment in Practice:
Industry Challenges and Opportunities

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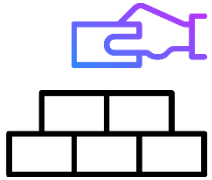
Introduction

IMDRF: Aim is to strategically **accelerate** international medical device regulatory **convergence** to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges while protecting and maximizing public health.

IMDRF **Conformity Assessment** Guidance: Aim is to **harmonize** the documentation and procedures that are used to assess whether a medical device **conforms** to the regulations that apply in each jurisdiction. **Eliminating differences** between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier **access** to new technologies and treatments.



What is the **industry experience** & how can we continue to **build** on the work done to date?

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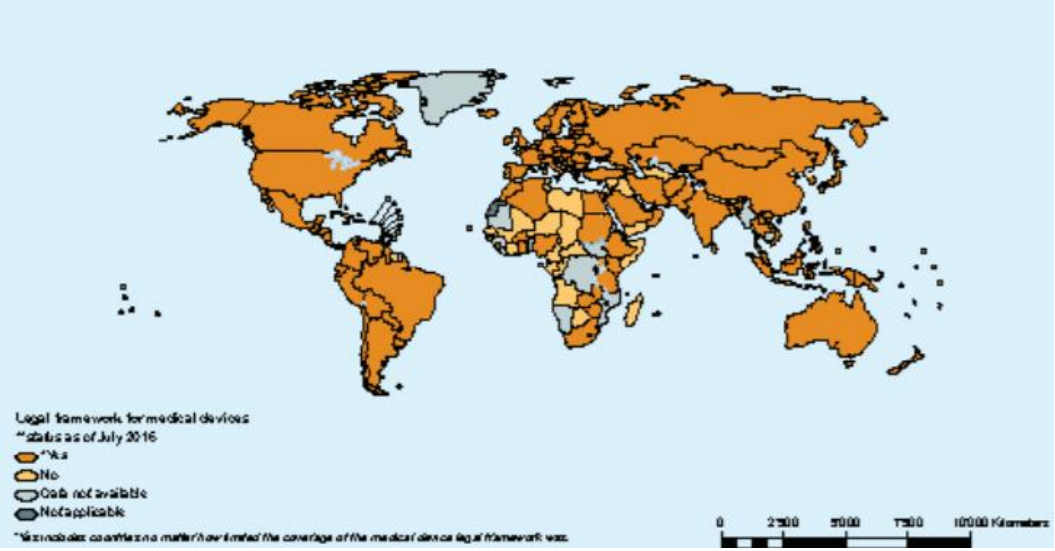
Global Map of Regulated Markets



*Source: Global Atlas of medical devices, WHO, 5 August 2017: https://www.who.int/publications/i/item/9789241512312

Industry Experience

- Complex global regulatory landscape.
- > 113 countries with a legal framework for medical devices*.
- Navigating multiple regulatory frameworks.
- Increased resource demands on QA/RA teams.

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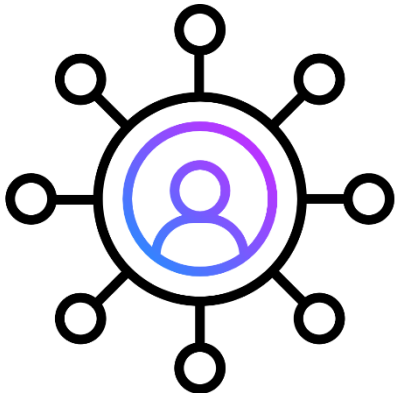
Key Challenges

↑ Requirements

Resources & bottlenecks

Divergent requirements



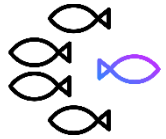
Audits & Inspections

Local standards

Lack of digitization

Pharma based legislation

Inconsistent interpretation



Case Study

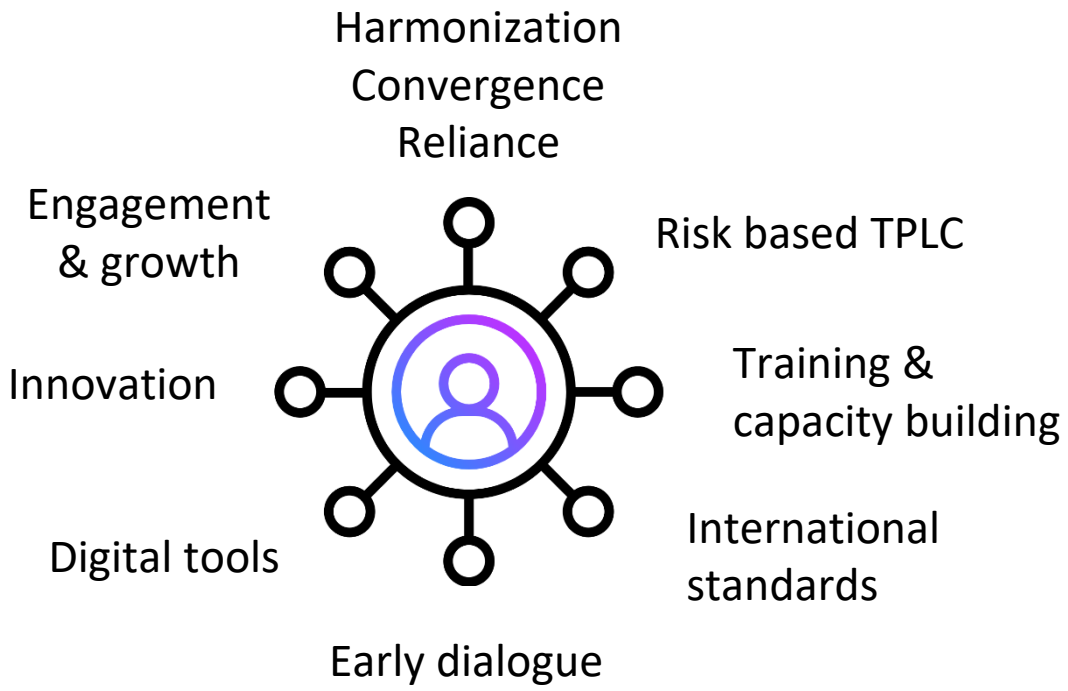
Drug Eluting Stent – Approval

Benefits: Optimal healing, ↑ deliverability, ↓ radiation exposure, ↓ procedure time, ↓ treatment cost.
Launch market approval: MC Country - 7 months

Market	Approval Timelines	Examples of Key Challenges	Status
Country Located in Europe (not EU)	2* yrs	Evolving framework, unique requirements, ↑ site audit…	Ongoing
Country located in Middle East	> 3* yrs	Pharma legislation – additional lab analysis…	Ongoing
Country Located in East Asia	~ 3* yrs	Type approval, local standards & clinical data, unique IFU…	Ongoing
Country Located in South Asia	5-6* yrs	Regulatory infrastructure not ready, capacity limitations at MOH…	Ongoing

* Expected timeline based on previous experience

Opportunities



Case Study

Drug Eluting Stent – Approval contd.

Market	Traditional Pathway	Approval Time	Examples of Key Opportunities	Status
Country located in SE Asia	8-10 months	9 months	International best practice & standards	Approved
Country Located in Oceania	12-18 months	20 days	Reliance	Approved
Country Located in South America	6-15 months	2 months	Reliance	Approved
Country located in Europe (not EU)	NA	2 months	Reliance	Approved

Impact & Recommendations

Poorly functioning conformity assessment pathways impact patient access to safe, high quality, effective and innovative medical devices.

Enhance global health equity by implementing convergent conformity assessment pathways, based on internationally recognized best practice & standards*.

Implement regulatory reliance, including recognition*.

*GMTA White Paper: The Need to Advance Global Convergence and Regulatory Reliance to Accelerate Access to Medical Technology, May 2023

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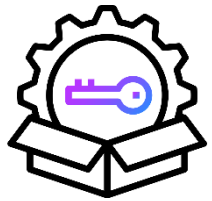
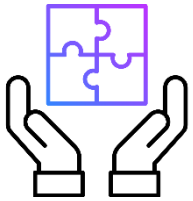
Conclusion



Conformity assessment is the key to patient safety, building trust & enabling global access.

Industry is committed to continued dialogue with IMDRF.



Shared vision – predictable, efficient and harmonized global regulatory frameworks.