IMDRF International Medical Device Regulators Forum

Medical Device Regulatory Reliance

Benefits and Opportunities

March 10, 2025

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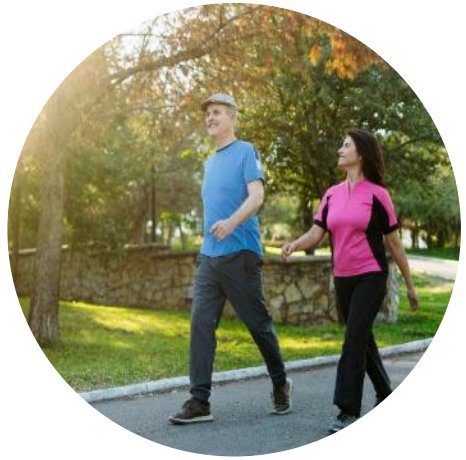
Overview

- Observations from IMDRF 25 Joint IMDRF-Industry Workshop on “Reliance” March 2024
- The Value of a Reliance Playbook & Foundational Principles
- Looking Ahead



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"Benefits and Opportunities of Medical Device Regulatory Reliance"

11 March 2024 White Paper

Pre Market	Post Market
Speeds access to patients of safe, effective, high-quality, innovative medical devices across the Total Product Life Cycle	Allows for faster identification of and communication about potential safety issues
Regulatory authorities maintain sovereignty and their own decision – making authority	Allows for appropriate allocation of local resources for post market activities .
Allows for knowledge sharing among regulatory authorities and reallocation of resources within a given regulatory authority without decrease in regulatory requirements	Use of internationally harmonized standards (e.g., ISO 13485) and IMDRF Technical Documents (e.g., **IMDRF/AET WG/N43: Terminologies for Adverse Event Reporting (AER): Terms, Terminology and Codes**); convergence to a common definition of significant and non-significant change
Trust, communication, clarity and transparency among regulatory authorities relying on one another is critical for successful reliance	Trust, communication, clarity and transparency among regulatory authorities relying on one another is critical for successful reliance
While convergence of regulatory frameworks enhances reliance, it is not a prerequisite for reliance	The MDSAP provides a **success story** of reliance for regulatory audits of manufacturers.

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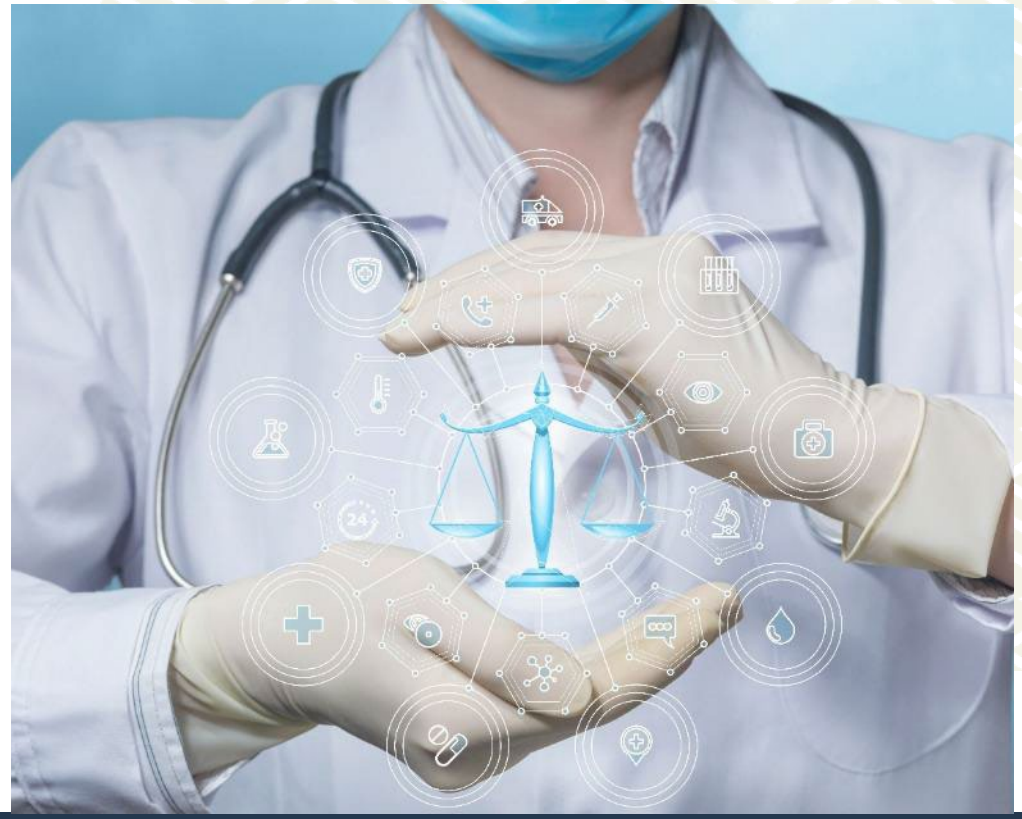
Outcomes: IMDRF 25 Joint Workshop on Reliance - March 2024

IMDRF plays a critical role in bringing stakeholders together to share experiences and build trust.

Future work for IMDRF to further reliance:

- Publication of a "**Reliance Playbook**" that includes general strategies, practical examples and recommendations for implementing a reliance program;
- Identification of which regulators within IMDRF have implemented reliance practices; and
- Training to support adoption of IMDRF technical documents and convergence of regulatory requirements.



The Value of a Reliance Playbook

Promote Understanding

- Educate stakeholders about the opportunities and benefits of the implementation of reliance

Encourage Collaboration

- Foster collaboration and trust among regulatory authorities by sharing knowledge and experiences
- Regulatory authorities maintain sovereignty on their own decision-making

Share Best Practices

- Provides strategies and practical examples of successful reliance models
- Recommendations of how reliance can be implemented in different regulatory environments, showcase flexibility
- Use of consensus standards to support reliance across the Total Product Life Cycle
- Examples of how to determine product “sameness”, despite differences in classification, product names

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RELIANCE
Foundational Principles

Founded in Law/ Country Legislation

- Transparent
- Public Comment

Medical Devices & In Vitro Diagnostics

- Not included under Medicines & Vaccines

Definitions & Criteria

- WHO Good Reliance Practices Guidance
- WHO Global Model Regulatory Frameworks

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A Challenge: Determining Product "Sameness"

Product Name Variations:
Product names may include or exclude codes/models, which can vary by region for traceability purposes.

Risk Classification Misalignment:
Differences in risk classification across regions.

Intended Use Discrepancies:
Variations in the stated intended use of products

A Solution: WHO Definition of Product "Sameness"

***"…two products have identical essential characteristics…"*[1]**

- **All relevant aspects** of medical devices and IVDs to be considered
- **Results of supporting studies of safety & performance**, indications, conditions of use
- **Potential, justified differences** to **be assessed** by the manufacturer (and the relying NRA)
- **Essential role of the manufacturer** to confirm the sameness of a product and to provide the same documentation to different NRAs

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Opportunities Realized through Reliance

- Faster Access to Safe, Quality Innovations
- Efficiency and Resource Optimization
- Enhanced decision-making, retain sovereignty
- Build trust and harmonization

Looking Ahead…

IMDRF Management Committee Recommendations

- Complete and refine the Reliance Playbook to:
  - Include practical information and real-world examples to help operationalize reliance
  - Ensure it meets the needs of regulatory authorities
  - Allow for flexibility
- Adopt WHO definitions for Reliance and Product Sameness[1]
- Reinforce Good Regulatory Practices and use of the WHO Good Reliance Practices[1]




Looking Ahead…

Industry Recommendations

- Support regulators as they operationalize reliance pathways and with determination of product sameness
- Share examples of reliance in practice by regulatory authorities
- **Use the Reliance pathway!**




1 Annex 10, WHO Technical Report Series, No.1033, 2021: Good reliance practices in the regulation of medical products: high level principles and considerations

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Thank you!

Any Questions?

Renata Brandao, Director Regulatory Affairs, Abbott
Diane Wurzburger, VP Regulatory, Quality and Global Policy, GE HealthCare
On behalf of GMTA & DITTA