IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

16:40 – 16:55

Global Medical Technology Alliance (GMTA)

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Global Medical Technology Alliance
Innovating for a Healthier World

Reliance White Paper

IMDRF Stakeholders Session

March 28, 2023

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Presentation Outline

- Background
- Foundational Principles
- Core Tenets
- Next steps

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Background

- Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices
- Small differences in standards, guidance and regulations can cause major differences in the regulatory path (e.g., MD/IVD classification)
- These differences are amplified during a pandemic and seen in countless emergency use pathways

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Foundational Principles

- Implement convergent regulatory frameworks based on internationally recognized best practices and standards.
- Implement regulatory reliance, including recognition
- Implement core tenets of medical device regulations

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10 Core Tenets

- Ensure predictability and adequate resources
- Support innovation and apply equal regulation to both domestic and international companies
- Adopt Good Regulatory Practices (GRP)
- Avoid requirements that lack a patient safety benefit

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10 Core Tenets

- Accept global clinical trial data and leverage Real World Evidence
- Implement a risk-based approach to product changes
- Avoid unnecessary barriers to access based on product country of origin

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10 Core Tenets

- Implement a single dossier
- Adopt electronic instructions for use
- Accept digital labels

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Next Steps

- Disseminate and promote the principles of global convergence and regulatory reliance

- Cooperate with global regulators to get reliance in practice, not just on paper