Global Medical Technology Alliance
Innovating for a Healthier World

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GMTA update

16th February 2023

Global Harmonization Working Party (GHWP) Annual Conference

Riyadh, Kingdom of Saudi Arabia

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Who Are We?

- GMTA is the Global Medical Technology Alliance
- Origins date to 1990s initially as informal network, formally established in 2010 in Switzerland
- WHO recognized NGO since 2015, official observer to the IMDRF since 2012 and **liaison member of GHWP since 2022**
- With more then 30 member associations, GMTA represents innovative medtech companies that develop and manufacture 85 percent of the world's medical devices, diagnostics and digital health solutions
- Some GMTA members also represent a significant number of distributors, particularly in countries that have little or no local manufacturers of medical technology

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Who Are We?

- GMTA's mission is to support the objectives of providing safe, effective and innovative medical technology that saves and enhances lives, benefiting people and society

- GMTA committees and WGs:
  - Global Diagnostic Alliance
  - Regulatory Affairs Committee
  - Market Access Committee
  - Ethics Committee
  - Africa WG

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Regulatory convergence and reliance

- 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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Regulatory convergence and reliance

- **Regulatory convergence and reliance advance smart regulation and underpin an efficient, resilient, and sustainable regulatory framework** - this can be achieved through:
- Implementing convergent regulatory frameworks based on internationally recognized best practices
- Applying regulatory reliance, including recognition – e.g., by recognizing or leveraging MDSAP certificates
- Implementing core tenets of medical device regulations

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GMTA's message

- Thank you for all GHWP's efforts to promote regulatory convergence and harmonization of medical device regulations among its members

- The global pandemic emphasized the value of regulatory cooperation and highlighted the opportunities to create efficiencies, enhance regulatory capacity and to accelerate access to medical technologies

- Essential to work with IMDRF and other stakeholders towards a common objective of achieving regulatory convergence and reliance to accelerate access to medical technologies

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GMTA's message

*"The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on **reliance** and trust."*