Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Global Medical Technology Alliance

GMTA Update

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Global Medical Technology Alliance
Innovating for a Healthier World

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

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 stakeholder 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

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

Who Are We?

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

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Core tenants of medical device regulation:

GMTA recommends the following approaches to key parts of the total product lifecycle:
Position Paper

01 Ensure predictability and adequate resources

02 Support innovation and apply equal regulation to both domestic and international companies

03 Adopt Good Regulatory Practices(GRP)

04 Implement a risk-based approach to product changes.

05 Avoid requirements that lack a patient safety benefit

06 Accept global clinical trial data and leverage Real World Evidence ("RWE")

07 Avoid unnecessary barriers to access based on product country of origin

08 Implement a single dossier

09 Adopt electronic instructions for use

10 Accept digital labels

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Thank you!

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