Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Global Medical Technology Alliance

GMTA Update

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Innovating for a Healthier World

29th GHWP Annual Meeting and 29th GHWP TC Meeting, 1th - 4th Dec 2025
Bangkok, Thailand

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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 stakeholder to the IMDRF since 2012 and a **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

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Who Are We?

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

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What is medical technology?

Link: GMTA WHO ‘what is a medical device ?’ :
https://www.youtube.com/watch?v=OVQ0b8HT_Q8

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GMTA position paper: **Exploring the Benefits of Reliance and the Medical Device Single Audit Program (MDSAP) for Manufacturing Site Audits Requirements - Link**

- The medical technology industry strongly supports a robust regulatory system that ensures the safety and performance of devices and promotes timely access of patients to lifesaving and life-enhancing medical devices.
- Industry advocates for the adoption of global convergence and regulatory reliance

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Benefits of global convergence and regulatory reliance

- Conserve and optimise the use of limited regulatory resources
- Elevate regulation to one high standard
- Accelerate access to safe, high quality, effective and innovative medical technologies

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Benefits of global convergence and regulatory reliance

- Facilitate environment conducive to growth, enhancing innovation and facilitating trade and jobs
- Enhance global health equity
- Reduce unintended consequences related to duplicative product site inspections resulting in potential barriers to trade with negative impact for patient access

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Convergence to international best practices and regulatory reliance provides an opportunity for both industry and regulatory bodies to ***reduce redundant audits where appropriate, improve resource allocation/utilization and enhance efficiency*** *of regulatory processes by enabling both to focus on those activities that are appropriately conducted at the local level by National Health Authorities.*

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Benefits of global convergence and regulatory reliance - MDSAP

- MDSAP is based on ISO 13485 enabling a single regulatory audit of a manufacturer's QMS to meet the requirements of multiple jurisdictions
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- Industry encourages reliance on MDSAP audits and MDSAP certificates

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Benefits of global convergence and regulatory reliance - MDSAP

- Non-MDSAP members may leverage MDSAP to streamline regulatory compliance and quality management processes
- By leveraging MDSAP audits as a replacement for local audits or a replacement for additional on-site audits, a more efficient use of regulatory resources can be enabled
- Strengthening the consistency, predictability, and transparency of regulatory programs, without compromising audit standards

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The medical technology industry welcomes additional conversations ***to share MDSAP case studies*** *and* ***provide additional insights to support consideration and implementation reliance on MDSAP***

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Thank you!

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