

Global Medical Technology Alliance

GMTA Update

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Global Harmonization Working Party

Towards Medical Device Harmonization

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 than 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



**Global Medical
Technology Alliance**
Innovating for a Healthier World



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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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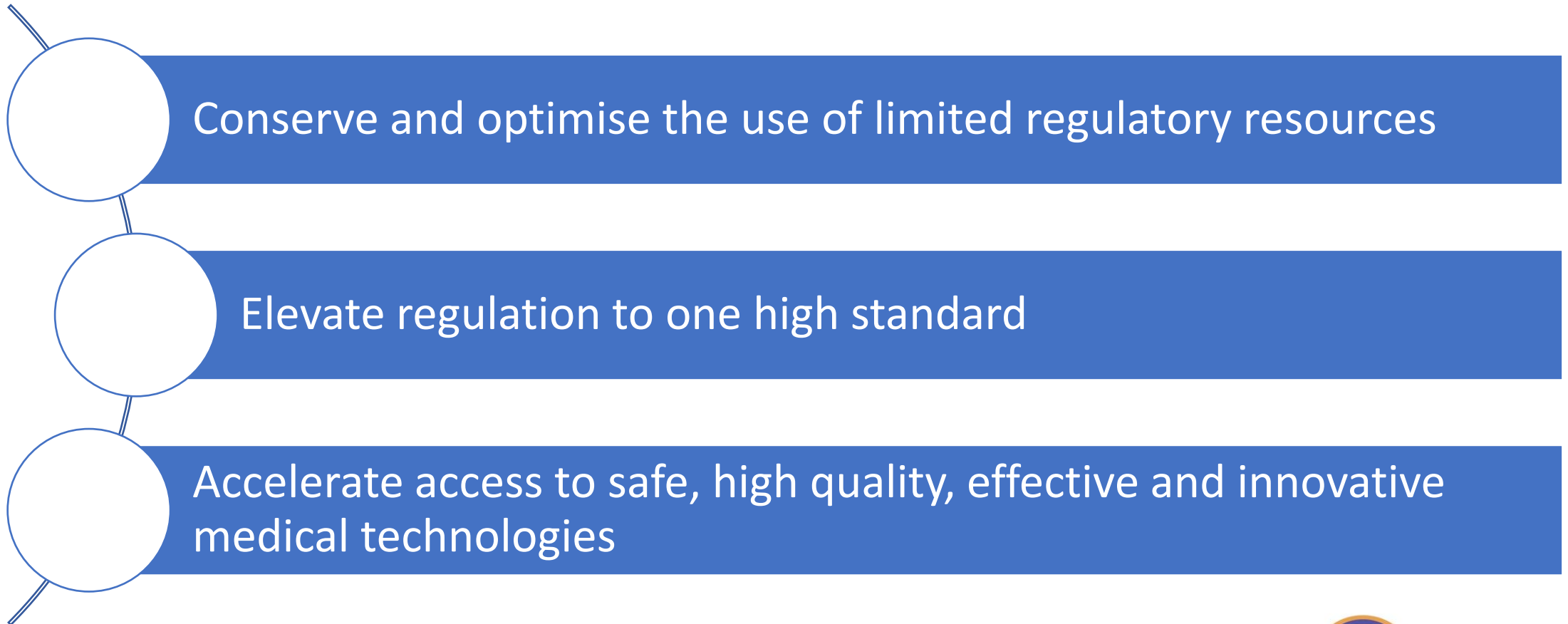


GMTA position paper: **Exploring the Benefits of Reliance and the Medical Device Single Audit Program (MDSAP) for Manufacturing Site Audits Requirements - [Link](#)**

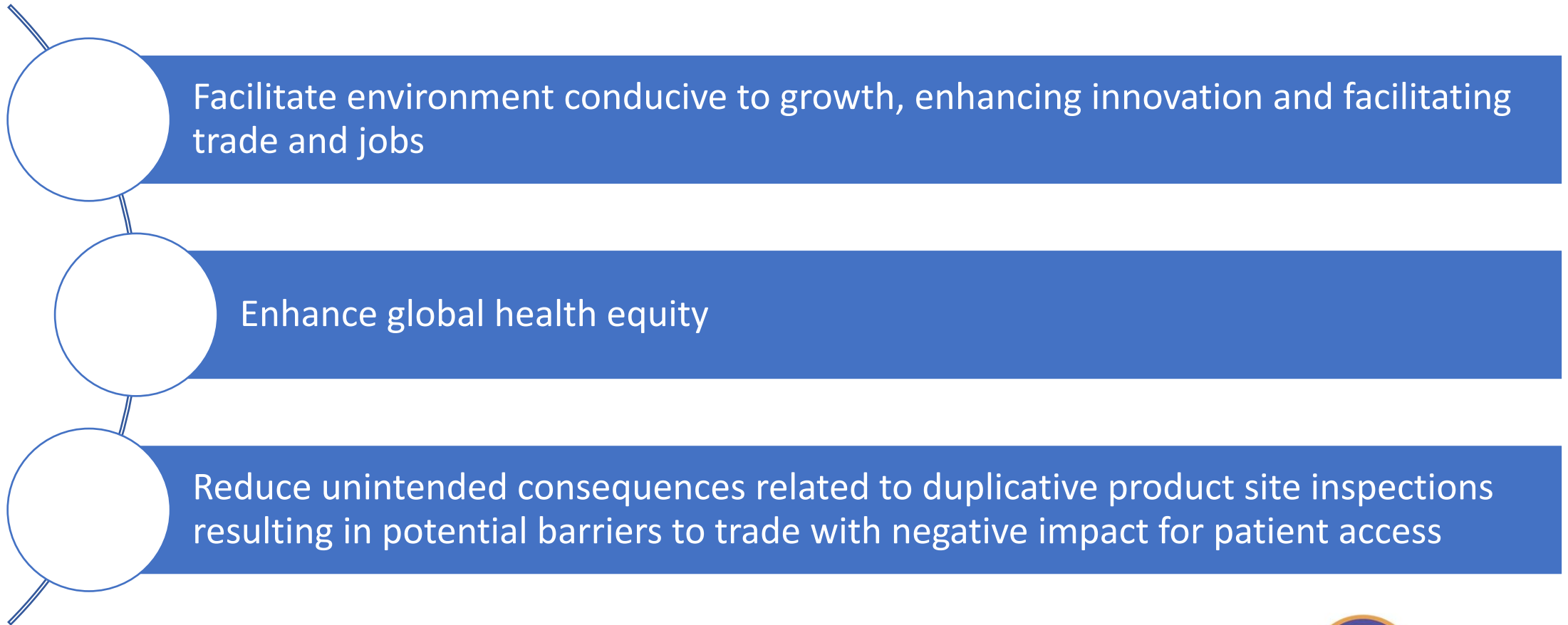
- The medical technology industry strongly supports a robust regulatory system that ensures the safety and performance of devices and promotes timely access of patients to lifesaving and life-enhancing medical devices.
- Industry advocates for the adoption of global convergence and regulatory reliance



Benefits of global convergence and regulatory reliance



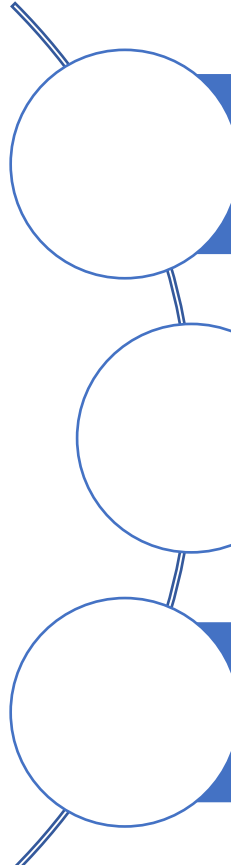
Benefits of global convergence and regulatory reliance



*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.*



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

Single regulatory audit of a manufacturer's QMS to meet the requirements of multiple jurisdictions

Industry encourages reliance on MDSAP audits and MDSAP certificates

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

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

Thank you!

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