



Global Medical  
Technology Alliance  
*Innovating for a Healthier World*

# **The Need for Advancing Global Convergence of Medical Technology Regulation**

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# Composition of GMTA: 26 associations

- **Advanced Medical Technology Association**
- **Association of British HealthTech Industries (ABHI)**
- **Middle East & North Africa Medical Technology Association**
- **Asia-Pacific Medical Technology Association**
- **International Medical Device Manufacturers Association**
- **Medical Technology Association of New Zealand**
- **Association of Research Based Medical Technology Manufacturers in Turkey**
- **Irish Medical Devices Association**
- **Mexican Association of Innovative Medical Devices**
- **Brazilian Association of Imported Medical Technology**
- **Irish Medical and Surgical Trade Association**
- **South African Medical Technology Industry Association**
- **Bundesverband Medizintechnologie**
- **IVD Australia Limited**
- **ASEDIM**
- **Câmara Brasileira de Diagnóstico Laboratorial**
- **The Japan Federation of Medical Devices Associations**
- **Association of National Enterprises of Colombia**
- **Canada's Medical Technology Companies**
- **Korea Medical Device Industry Association**
- **Global Medical Device Nomenclature**
- **Chinese Medical Devices Industry Association**
- **Medical Imaging & Technology Alliance (MITA)**
- **Medical Technology Industry of Denmark**
- **Medical Technology Association of Australia**



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# **White Paper - Global Convergence of Medical Technology Regulation**

- White Paper adopted by GMTA in April 2017
- Key elements to promote convergence



# Global Harmonization Movement

- Thanks to GHTF and now IMDRF, international regulatory convergence has been underway for nearly 20 years
- GMTA applauds IMDRF for coming together to:
  - Build on the strong foundational work of the GHTF
  - Accelerate international regulatory convergence
  - Advance harmonization based on international standards



# Impact of Differing Regulations

- Patient access to life saving products
- Patient access to quality products in a efficient time period
- Drain on administrative and regulatory agency resources
- Opportunity costs – funds could be used for research to support new innovation
- More difficult to comply



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# Key Elements to Promote Convergence

1. Implement GHTF & IMDRF guidance documents
2. Issue regulations that are clear, consistent, and transparent
3. Allocate appropriate resources to support implementation of convergence initiatives
4. Ensure regulatory decisions are based on science
5. Adopt international standards



# Global Convergence Benefits

## For Regulators

- Convergence of regulatory requirements promotes innovation of new health technologies and greater access for patients to these products.
- Supports efficient use of vital resources.

## For Industry

- Creates a transparent, efficient, and predictable regulatory environment focused on innovation and driven by patient needs.
- Reduces regulatory redundancy that pulls resources away from research and development.



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**Thank You**

**谢谢**