



Global Medical
Technology Alliance
Innovating for a Healthier World

Advancing Global Convergence of Medical Technology Regulation

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Outline

- Principles for Advancing Global Convergence
- Impact of Differing Regulations
- Global Harmonization Movement
- Key Elements to Promote Convergence
- Global Convergence Benefits
- Recommendations to Support Convergence



Principles for Advancing Global Convergence

- **Health & Safety**
 - Right to protect health and safety and to establish regulations to determine safety and quality
- **A Proportionate Approach**
 - Application of the principle of proportionality to regulation (use the least burdensome measure)
- **Transparency, Efficiency and Predictability**
 - Transparent, efficient and predictable regulatory controls



Impact of Differing Regulations

- Market entry hurdles
- Increased costs
- Technical barriers that impede trade
- ***MOST IMPORTANTLY, delay in patient access to medical technologies***



Global Harmonization Movement

- Thanks to GHTF and now IMDRF, international regulatory convergence has been underway for nearly 20 years
- Training needed to ensure consistent application of IMDRF and GHTF guidance documents
 - APEC Medical Device Priority Work Area established
 - GMTA pilot training proposal



Key Elements to Promote Convergence

- Implementation of GHTF & IMDRF guidance documents into national laws
- Regulator training programs to ensure consistency in implementation
- Adoption of international consensus standards
- Reliance on regulatory decisions (MDSAP)



Global Convergence Benefits

Promotes Public Health

- Supporting innovation/development of new therapies
- Creating opportunities for regulator to regulator collaboration
- Fosters transparent engagement from industry
- Strengthening industry compliance with regulatory requirements

Provides opportunity for regulatory reliance

- Leveraging resources by regulators

– ***MOST IMPORTANTLY FOR PATIENTS***

Improve patient timely access to life-saving and life-sustaining technologies around the world

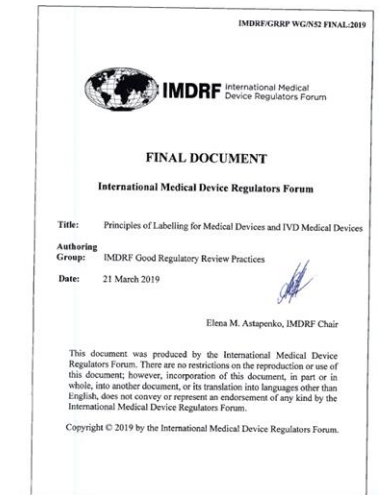


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Principles of Labeling for Medical Devices and IVD Medical Devices

Aligned labelling interpretation has a significant impact on market access and efficiency for the regulators and for the MedTech industry.

Recognition and/or use of ISO symbols and E-IFU adoption are key to enhance patient access.



<http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>



Recommendations to Support Convergence

- Interactions with other harmonization groups
- Inclusion of industry experts in relevant IMDRF working groups
- Inclusion of experts from non-IMDRF regulators on working groups
- Support training programs on IMDRF documents
- Measure progress on implementation of guidance documents