Advancing Global Convergence of Medical Technology Regulation

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Philippe Auclair
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
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.

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