GMTA
- Collaboration with IMDRF -
About GMTA:

➢ Who are we?

➢ What do we do?

➢ How do we work with IMDRF?
1990s  Origins date as informal network
2010  Formally established
2013  Became legally constituted in Switzerland as an “association”
2015  WHO approved as official NGO

• Governed by Articles of Association, Governance Rules, Elected Board of Directors

◆ Membership open to medical technology associations (not companies)
  - willing to accept GMTA governance rules
  - with functioning code of ethical business practices
Countries Represented by GMTA
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ABHI (UK), Abimed (Brazil), AdvaMed (USA), AMID (Mexico), ANDI (Columbia), APACMed (Asia Pacific), ARTED (Turkey), BvMED (Germany), CAMDI (China), CBDL (Brazil), Eucomed (Europe), EDMA (Europe), IMDA (Ireland), IMEDA (Russia), IMSTA (Ireland), IVD Australia (Australia), JFMDA (Japan), KMDIA (Korea), Mecomed (Middle East), MEDEC (Canada), MEDICOINDUSTRIEN (Denmark), MTAA (Australia), MTANZ (New Zealand), SAMED (South Africa), THAIMED (Thailand)
Covers Almost All Markets*

- Americas: 44% (20%)
- Western Europe: 25.4% (20%)
- Asia/Pacific: 22.2% (15%)
- Middle East/Africa: 2.8% (11%)
- Central and Eastern Europe: 4.8% (100%)

*(x)=share of region not covered by GMTA

Source: Espicom
Covers All Sectors

- Electrodagnostic: 13.7%
- Orthopaedic & Prosthetic: 11.8%
- Patient Aids: 9.0%
- IVD: 10.3%
- Dental Instruments & Supplies: 3.8%
- Dental Capital Products: 1.3%
- Imaging Accessories: 5.0%
- X-Ray Apparatus: 4.5%
- Syringes, Needles, & Catheters: 8.0%
- Other Consumables: 1.7%
- Woundcare: 3.5%
- Others: 27.4%

Source: Espicom
Our Mission

The mission of GMTA is to support the objectives of providing safe, effective and innovative medical technology that saves and enhances lives, benefiting people and society.
What do we do?

- General Assembly and Board meet twice/year
- Provides a forum in which Members exchange information and jointly develop and advocate policies that encourage innovation in medical technology to address patients’ healthcare needs on a global basis.

Examples include:
- Collaboration with IMDRF
- Support of WHO
- Exchange info. about Economic Corporation (TPP, EPA)
How do we work with IMDRF?

IMDRF

DITTA

GMTA

Sub-Committee

Member Industry

Member Industry

Member Industry

Member Industry

Member Industry

Member Industry
GMTA-IMDRF Work

- Support IMDRF goal of regulatory harmonization
- Support transparency as guiding principle
- Support capacity considerations for new projects
- Proposals to IMDRF:
  e.g.
  - promote global acceptance of UDI systems
  - ability to comment on proposed NCAR changes
  - convergence in use of major standards
GMTA-IMDRF Work

- GMTA Subcommittee on IMDRF Regulatory Policies
  - Currently Working: UDI, SaMD, RPS, Registry

- Participate in IMDRF Management Committee

- Provide expertise and company representatives to IMDRF working groups (UDI, RPS, Software)

- Appreciate outreach to industry on MDSAP pilot
Work with other int’l organization

With WHO: Discuss about

- International Procurement (Product Specifications)
- Response to the Ebola crisis
- UNGA NCD conference recommendations
- EHT (Essential Health Technologies)
- Injection safety
- Priority Medical Devices Project
- Pandemic Influenza Preparedness Framework
- pre-qualification tendering policy/program
- Adoption of GMDN (Global Medical Device Nomenclature)
- WHO Global Medical Device fora (2010, 2013)
ありがとうございました。

Thank you for your kind attention!