

Global Medical Technology Alliance Innovating for a Healthier World

GMTA

- Collaboration with IMDRF -



About GMTA:

>Who are we?

>What do we do?

How do we work with IMDRF?

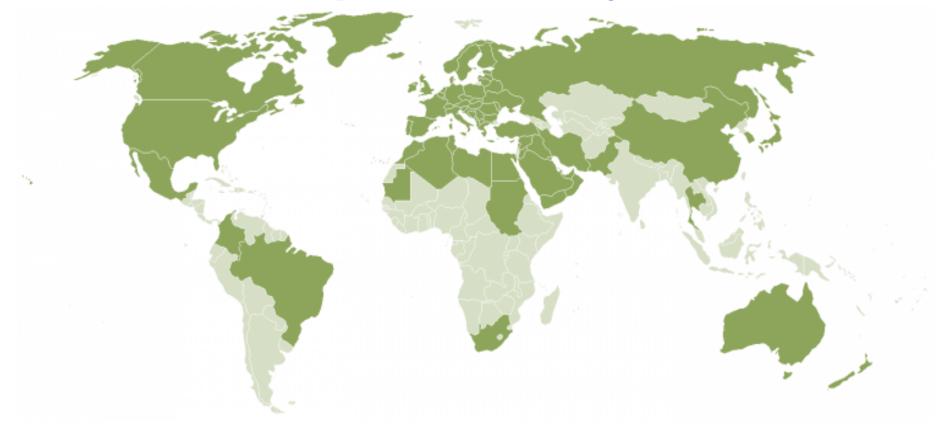


Who Are We?

- **1990s Origins date s 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





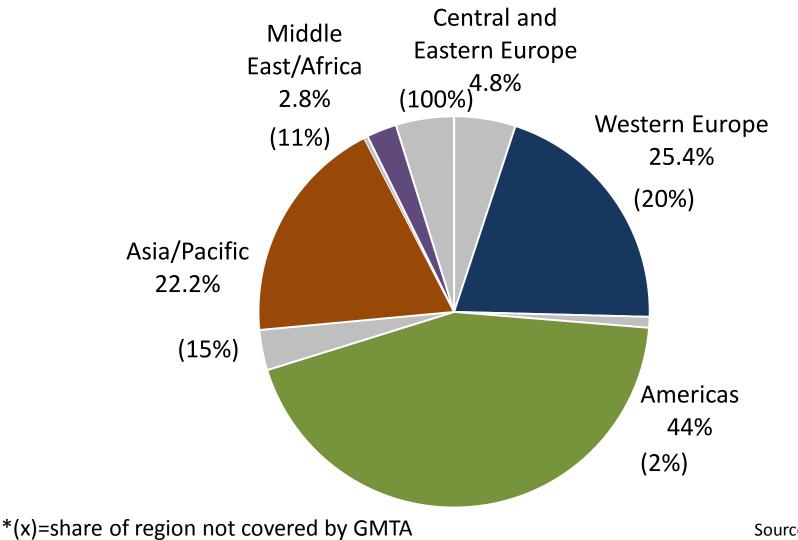
Countries Represented by GMTA

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)



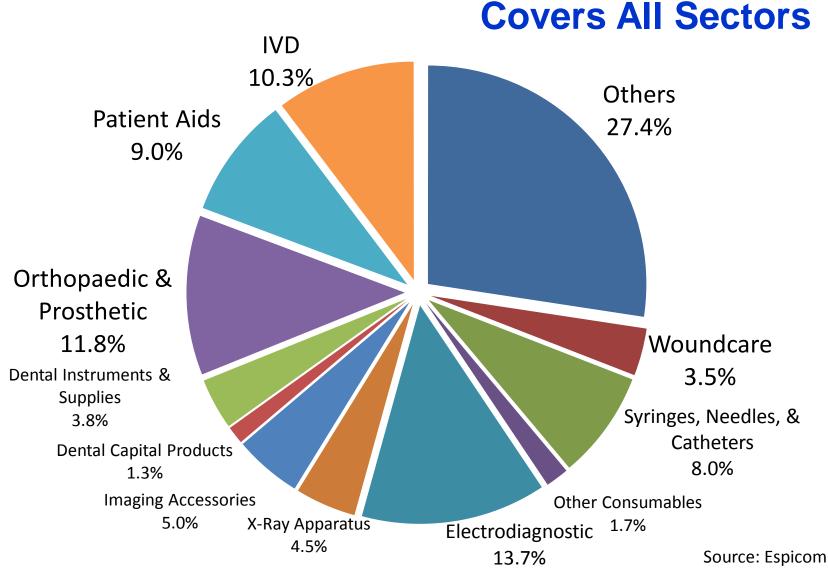
Global Medical Technology Alliance Innovating for a Healthier World

Covers Almost All Markets*



Source: Espicom







What do we do?

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

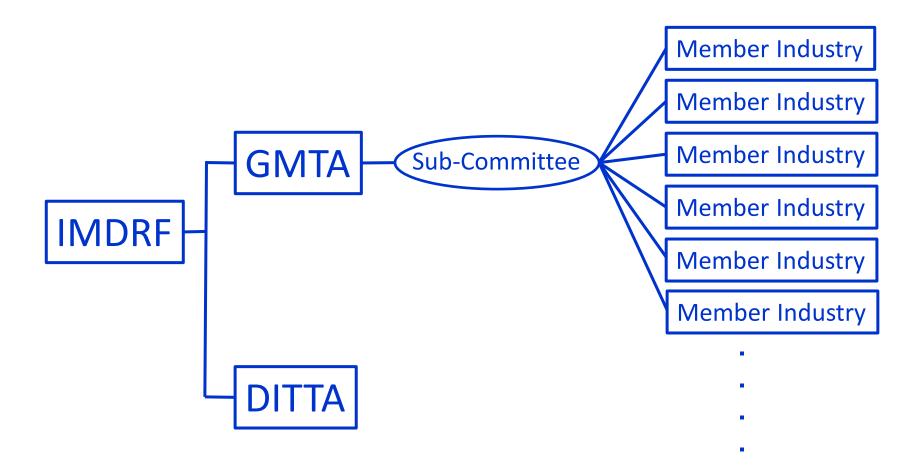
Provides a forum in which Members exchange information and jointly develop and advocate policies that encourage innovation in medical technology to address patients' healthcare needs on a global basis.

Examples include:

- Collaboration with IMDRF
- Support of WHO
- Exchange info. about Economic Corporation (TPP, EPA)



How do we work with IMDRF?





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)





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ありがとうございました。 Thank you for your kind attention!