Future of Global Regulatory Harmonization
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About GMTA

- GMTA members: national or regional medical technology associations (currently 25), covering economies as diverse as China, Brazil, EU, S. Africa, US, Australia, Japan, Canada, NZ, Middle East

- Associations represent innovative companies that develop and manufacture 85% of the world’s medical devices, diagnostics and equipment

- GMTA provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients’ healthcare needs
Current Regulatory Status

• Currently 85 countries regulate medical devices

• Regulations are in development in other countries

• GHTF regulatory model possible basis for device regulation

• Experience from other harmonization initiatives can be informative
Calls for Harmonization

- Calls for harmonization of regulatory approaches coming from many sectors:
  - Governments
  - Industry
  - Public
- Are sectors calling for the same thing?
Why Harmonize?

- Provide consistent application of regulatory principles and practices
- Reduce duplication
- Decrease time and costs
- Facilitate international trade
- Allow new products/technologies to enter the market
- Create transparent regulatory processes
Harmonization Efforts

- Asia: Asian Harmonization Working Party; ASEAN
- Latin America: PanAmerican Health Organization; Mercosur
- Asia Pacific Economic Cooperation forum
- IMDRF focus on implementation in key areas:
  - Single audit program
  - UDI
  - Regulated product submission—standard table of contents
Harmonization Process

• Harmonization is consistent with policies of many regulatory authorities

• Regulatory programs are expected to:
  ➢ Use available international standards/guidelines as basis for technical regulations
  ➢ Proactively influence their developments, as appropriate
  ➢ Consult with stakeholders/public
Challenges to Harmonization

• Convergence versus harmonization

• Uptake and implementation by regulatory bodies
  ➢ Countries with mature regulatory systems would require changes in laws/regulations
  ➢ Countries with limited regulations attempting to implement full system

• Tendency of some countries to use regulations to protect domestic industry
Recommendations

Harmonization discussions today lead to the common regulatory framework of tomorrow

- Build on the foundation established by the GHTF
- Learn from the experiences of other harmonization initiatives
- Introduce regulations consistent with available resources
- Move toward the realization of global harmonization on a step-wise approach
Thank You!