Global Harmonization Task Force

Larry Kessler, Sc.D.
FDA, Chair GHTF
Janet Trunzo
AdvaMed, Vice Chair

Key Themes

- GHTF Background
- Program of work
- Emerging Asian harmonization
- Emerging device issues
- GHTF and the Future

Why GHTF?

- The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

More Why?

- Serves as an information exchange forum
- Countries with medical device regulatory systems under development can benefit from others' experience
- May pattern their practices upon those of GHTF founding members
- Avoid unnecessary (new) regulatory requirements

What: Organization

- Founded in 1992
- Steering Committee made up of equal number of industry and government regulators
- The chair rotates among the government regulators, held from January 2007-July 2008 by the US

What: Study Groups

Study groups are the engine of GHTF guidance development (over 30 posted)

- SG1: Premarket conformance
  - (Chair, Dr. Ginette Michaud, FDA)
- SG2: Postmarket vigilance/surveillance
  - (Chair: Jorge Garcia, TGA Australia)
- SG3: Quality Systems
  - (Chair: Egan Cobbold, Health Canada)
- SG4: Auditing
  - (Chair: Markus Zobrist, Swissmedic)
- SG5: Clinical effectiveness
  - (Chair: Dr. Susanne Ludgate, MHRA UK)

So What? Successes?!

- Adverse event reporting
- Health Canada maintains the electronic National Competent Authority Report (NCAR) system
- ISO 13485 and FDA Quality System Requirements
- Auditing strategies and format close
- Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- GHTF served as basis of Australian system!

Where are we headed?
Taking the Task Force Forward

- Guidance Implementation
- Organizational Logistics
- Expansion

Implementation

- Implement guidance documents
  - FDA making a concerted effort: working on 7 guidance documents
- Single audits used in multiple jurisdictions!
  - Canada-Australia and Canada-EU agreements
  - FDA-Canada Pilot Multipurpose Audit Program
  - FDA-EU discussions beginning on possible pilot
  - Encourage use of the AP (Accredited Persons)
- Improve operation of the National Competent Authority Report system

Organizational Logistics

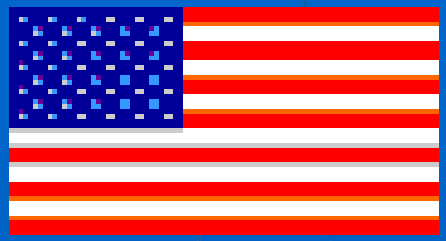
- Enhance web site utility and visibility
  - Attempt to create definitive regulatory source
  - Increased document availability: for example, *GHTF presentations on website*
  - Provide for links to translated documents
    - PAHO translated into Spanish and Portuguese
    - For example, can we documents in Mandarin?

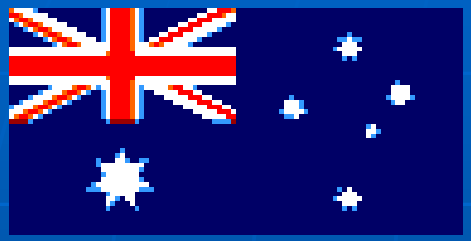
Expansion

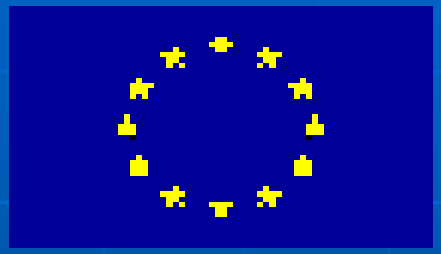
- Involve other countries, esp. AHWP, PAHO
- Work with ISO, IEC, others who share the GHTF mission
- GHTF Training Plan

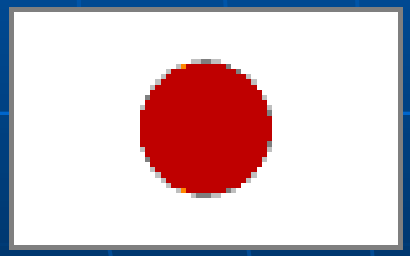
The Future is Now

- The GHTF has accomplished much
- Time to document those accomplishments
- Let's then build on this foundation and truly move toward the realization of global harmonization









Thank You …