



Global Harmonization Task Force

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Key Themes

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





GHTF Purpose

- 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.



Basic Principles

- 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
 - Wasteful for governments and industry
 - Delays technologies to the patient bedside



What is GHTF: Organization

- Founded in 1992
- Steering Committee (SC) composed of equal number of industry and government regulators
- The chair rotates among the government regulators, assumed by Health Canada July 1, 2008
- Work done by Study Groups and Ad Hoc committees reporting to SC



What: Study Groups

Study groups are the engine of GHTF guidance development (almost 40 posted)

- SG1: Premarket conformance
- SG2: Postmarket vigilance/surveillance
- SG3: Quality Systems
- SG4: Auditing
- SG5: Clinical effectiveness



Basic Work Program: SG1/5

- What is a manufacturer?
- Registering devices on the market
- Device risk classification
- Criteria for safety, and effectiveness or performance
- How do devices get on the market?
- Are clinical studies needed?
- Conduct and reporting of clinical studies



Basic Work Program: SG2/3/4

- What is a medical device adverse event?
- What should be reported, to whom, when, in what format?
- What defines the quality system requirements under which devices are produced?
- What is the system for monitoring quality systems and production?



GHTF 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 finalized
- 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!



Controversies

- Classification of devices: 3 vs. 4 classes
- When is “clinical evidence” needed and to what degree – considerable variation
- The Founding Members have work to do on implementing the GHTF documents, and also opening up the GHTF process to other countries that are becoming significant consumers and producers of medical devices

Emerging Device Issues



- New products
 - Combination products
 - Software driven
 - Software as devices
 - “Omics” diagnostics
- Outsourcing
- Hospital to home care
 - Environmental issues
 - Use issues



Special Topic Ad Hoc Groups

- Medical device software
- Combination Products
- Training
- Global Regulatory Model
- Global Medical Device Nomenclature



Nomenclature

- Global Medical Device Nomenclature:
 - Developed over the past ten years
 - In use in Australia, EU now translating
 - Governance needs addressing
 - Countries having an interest will have a say in governance
 - Legal and intellectual property (IP) issues now under exploration



Unique Device Identification

- Not if, but when
- World may be converging to GS1
- New requirement in USA
- Development of a standardized system of unique device identifiers (UDI)
- Placing UDI in human readable and AutoID on device, its labeling, or both
- Creation of the UDI Database – for each UDI, it contains the Minimum Data Set:
 - UDI, and the information used to create it, and
 - Information for Safe Use (e.g., indications, latex)



Issues to Consider

- GMDN linkage
- Serialization – anti-counterfeiting
- Emergency preparedness issues
- Combination products, kits (w, w/o drugs) – pedigree issues
- Reprocessed devices; SUDs
- Legacy devices
- Triggers for a “new” identification #
- Devices in production that now do not have Production Identifiers?



GHTF Expansion

■ Asia

- ASEAN and commitment to GHTF
- AHWP liaison member to GHTF
- Participation on Study Groups

■ Latin America

- Working toward liaison membership



Where are we headed? Taking the Task Force Forward



- Guidance
Implementation
- Organizational
Logistics
- Expansion



Implementation

- Implement guidance documents
 - Direct adoption by regulator authorities
- Single audits used in multiple jurisdictions!
 - Canada-Australia and Canada-EU agreements
 - FDA-Canada Pilot Multipurpose Audit Program
 - 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

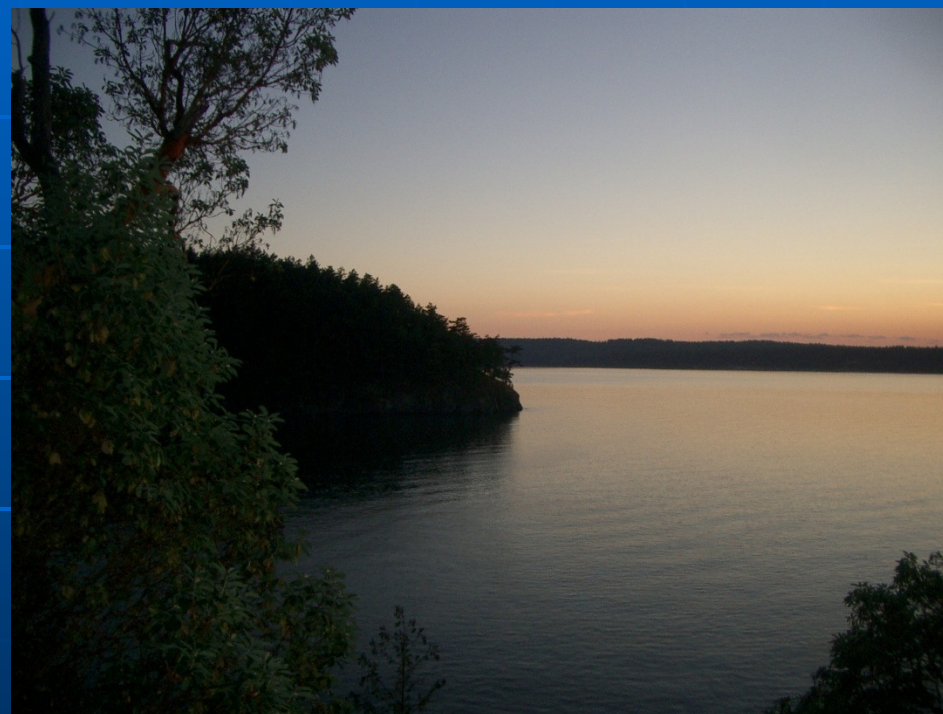


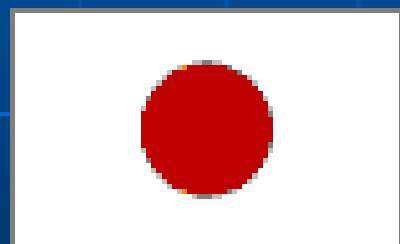
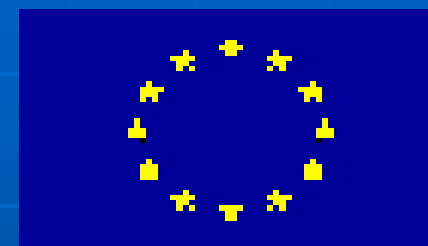
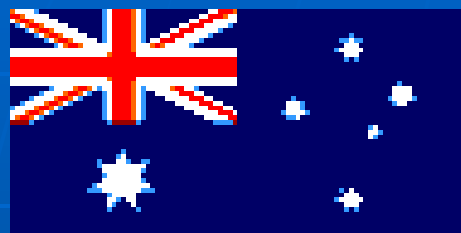
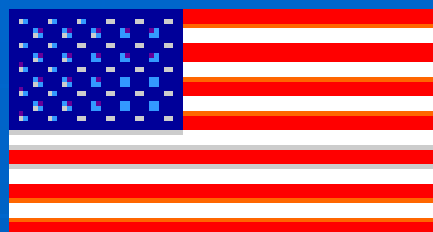
Expansion

- Work with ISO, IEC, others who share the GHTF mission
- GHTF Training Plan
 - Letter to go out this spring inviting organizations to become training partners
 - Continue to work with APEC on training
- Involve other countries
 - Translate guidance
 - Join NCAR
 - Adopt guidance with feedback to GHTF

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 ...