Global Harmonization: Fact or Fiction

Dr. R.G. Rotter
Chair of GHTF
and
Director, Medical Devices Bureau
Health Canada

Key Themes

- Emerging harmonization
- Emerging device issues
- The Future

Call for Harmonization

The call for harmonization of regulatory approaches is coming from many sectors:

- Governments
- Industry
- Public

Why Harmonize?

- Regulatory harmonization should:
  - Provide consistent application of regulatory principles and approaches
  - Improve regulatory system effectiveness and efficiency
  - Reduce duplication
  - Rationalize time and costs
  - Allow new products/technologies to enter the market place
  - Create transparent regulatory processes

Potential Challenges to Harmonization

- Differences in delegation of regulatory authorities between levels of government within a country
- Geo-political issues
- Consistency in the degree of implementation

Harmonization of Medical Device Regulations

- Harmonization is consistent with the policies of many regulatory authorities
- Regulatory programs are expected to:
  - use available international standards/guidelines as basis for technical regulations
  - proactively influence their development, as appropriate
  - Consult with stakeholders/public

Harmonization and the GHTF

- GHTF was created in 1992 by Canada, European Union, Japan, USA and Australia
- Informal grouping of medical device regulators and industry
- Currently consists of a Steering Committee, 5 Study Groups and several Ad Hoc Groups
- Has links with several partners including: ISO, IEC, WHO, PAHO, AHWP

GHTF Purpose

- 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

and

- to serve as an information exchange forum through which countries with medical device regulatory systems can benefit from the experience of other members

Organizational Structure

GHTF Areas of Activity

- Classification system and vocabulary
- Technical (science) requirements
- Format and content of marketing applications
- Assessment and review practices
- Post-market activities
- Quality Management Systems requirements and audits
- International standards

Special Topics: Ad Hoc Working Groups

- Medical device software
- Combination Products
- Training
- Global Regulatory Model
- Global Medical Device Nomenclature
- Unique Device Identifiers
- GHTF Administrative processes

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

Accomplishments

- ✓ Risk-based classification system
- ✓ Common definitions and vocabulary
- ✓ Global Medical Device Nomenclature
- ✓ Technical (science) requirements
- ✓ Format and content of marketing applications (STED)
- ✓ Assessment and review practices
- ✓ Post-market activities
- ✓ Quality Management Systems requirements and audits
- ✓ Use of international standards

Accomplishments

- ✓ Adverse event reporting
- ✓ 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

Why is GHTF's Work Important?

GHTF discussion today leads to the common regulatory framework of tomorrow

- Guidelines provide a scientifically sound, internationally harmonized means of establishing the quality, safety and efficacy of new devices: *'common regulatory platform, tools'*
- Improved transparency, predictability and efficiency of the medical device review process
- Reduces regulatory burden and promotes industry compliance
- Harmonized regulatory model for all countries

Why is GHTF's Work Important?

- Promotes trade, innovation and a more modern, risk-based approach to regulation
- Level playing field for industry in all countries
- Promotes regulatory communication and cooperation
- Facilitates the earlier availability of new devices and technologies
- Serves as a mechanism to avoid disharmony in technical requirements and for establishing regulatory considerations where science in flux

Why is GHTF's Work Important?

- To bring global perspectives, issues, experience and knowledge to bear on formation of state of the art international guidelines
- To better understand, prepare for and implement such guidelines from knowledge of issues and considerations that shaped them
- To establish and maintain productive working relations with other regulators, organizations and regulated industry
- To remain scientifically current
- To provide leadership internationally

Expansion

- Work with AHWP, Latin American Countries, ISO, IEC and others who share the GHTF goals
- GHTF Training Plan
  - Invitation has been extended inviting organizations to become training partners
  - Continue to work with APEC on training
- Involve other countries
  - Translate guidance documents into other languages
  - Join National Competent Authority Report system (NCAR)
  - Adopt guidance with feedback to GHTF

GHTF Model

- Guidance documents available in English on the GHTF website: *www.ghtf.org*
- Links provided to translated documents
  - PAHO translated into Spanish and Portuguese
- Training on the GHTF model and guidance documents
  - APEC sponsored
  - Training Partners Initiative

Adoption of GHTF Model

- GHTF Founding members
- Asia
  - ASEAN countries to adopt GHTF model
  - Asia Harmonization Working Party is a liaison member to GHTF
  - Participation on Study Groups
- Latin America
  - Working toward liaison membership

The Future is Now

- The GHTF has accomplished much
- The time has come to build on this foundation and truly move toward the realization of <u>global harmonization</u>