International Medical Device Regulatory Harmonization

*Reality or Fantasy?*

Second Annual Medical Device Regulatory, Reimbursement and Compliance Congress
Harvard University; 28-30 March 2007

M. Gropp; Medtronic, Inc., Minneapolis, USA
Caveats

- Complex topic in brief overview
- Personal views
What is regulatory “harmonization”? 

• Progressive convergence over time of regulatory requirements and practices

• Progressive elimination or reduction of technical differences in regulatory requirements
What is regulatory “harmonization”? 

• Progressive convergence over time of regulatory requirements and practices 

• Progressive elimination or reduction of technical differences in regulatory requirements 

• Not: 
  • Mutual recognition agreements 
    • mutual recognition of competence of other party to assess according to differing requirements 
  
• “Approved once – accepted everywhere”
International medical device regional regulatory harmonization initiatives
Global Harmonization Task Force (GHTF) History

- Informal grouping of medical device regulators and industry
- Began in 1992
- Canada, European Union, Japan, USA
  - Australia joined in 1993
  - “Founding Members”
  - Other interested countries are “Participating Members”
- Analogous to International Conference on Harmonization (ICH) in pharmaceutical sector
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 ...”

Source: GHTF
GHTF

Purpose (cont’d):

“.... the primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. These documents can then be adopted / implemented by member national regulatory authorities ...”

Source: GHTF
GHTF

Purpose (cont’d):

“.... GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.”

Source: GHTF
GHTF Organization Structure

Study Group 1
- Regulatory systems
- Premarket assessment

Study Group 2
- Vigilance reporting
- Market surveillance

Study Group 3
- Quality system requirements

Study Group 4
- Quality systems auditing

Study Group 5
- Clinical evidence
International Harmonization: Reality or Fantasy?

GHTF guidance documents

URL: http://www.ghtf.org

Proposed and final guidance documents
GHTF

Implementation

• GHTF guidance substantially adopted in requirements of Australia, Canada, EU, and Japan

• Substantial differences remain in interpretation and application

• Most progress in Quality Management System requirements and use of standards in premarket conformity assessment

• Harmonization efforts have had important collateral effects in bilateral initiatives and sharing of information amongst regulators
International Harmonization: Reality or Fantasy?

Forces driving medical device regulation in countries/regions outside GHTF founders

- Policy objective to protect public health
- Rising public expectations of access to health care
- Rising domestic industry
- Control of trade (import and export)
- Concerns about used/second-hand equipment being placed on local market
- Lending institution interests

Opportunity for prospective, rather than retrospective, harmonisation?
Asia-Pacific medical device regional regulatory harmonization initiatives
Asian Harmonization Working Party (AHWP)

- Formed in 1996-7
- Informal grouping
- Regional economy regulators and industry representatives

Brunei Darussalam
People’s Republic of China
Hong Kong SAR
Indonesia
Korea
Malaysia (Chair – Ministry of Health)
Philippines
Saudi Arabia
Singapore
Chinese Taipei
Thailand
Vietnam
Asian Harmonization Working Party

Purpose:

“... To study and recommend ways to harmonize regulation in the Asian region with global trends and to work in coordination with the Global Harmonization Task Force and APEC. ...”

Source: AHWP Terms of Reference
Asian Harmonization Working Party (AHWP)

Work program for 2005-2007

- Comparative study on existing medical device regulations in AHWP member economies
- Harmonization of definition, classification and nomenclature within AHWP
- Formalization of a post-marketing alert system
- Capacity building through training
- Work toward common submission dossier in alignment with ASEAN ACCSQ MDPWG
- Funding
International Harmonization: Reality or Fantasy?
Asia-Pacific medical device regional regulatory harmonization initiatives

- GHTF
- AHWP
- PAHO
- LAHWP
Pan American Health Organization

“RESOLVES:

2. To support the proposal to form an ad hoc group to promote and facilitate the medical devices harmonization processes in the Americas.

3. To urge the Member States to:
   (a) develop and strengthen their programs for the regulation of medical devices;

   (b) promote and support the participation of their regulatory authorities at the general meetings of the Global Harmonization Task Force (GHTF) and those of its four study groups, while promoting the use of GHTF documents in their programs for the regulation of medical devices.”

Source: Pan American Health Organization: 42nd Directing Council, 28 Sept. 2000 Provisional Eighth Meeting
Asia-Pacific medical device regional regulatory harmonization initiatives

- GHTF
- AHWP
- PAHO
- LAHWP
- APEC Funded Training Seminars
APEC funded regional regulatory training
APEC funded regional regulatory training
Asia-Pacific medical device regional regulatory harmonization initiatives

- GHTF
- AHWP
- PAHO
- LAHWP
- APEC Funded Training Seminars
- ACCSQ
- MDWPG (ASEAN)

International Harmonization: Reality or Fantasy?
International Harmonization: Reality or Fantasy?

ASEAN ACCSQ MDPWG

- ASEAN Economic Minister Meeting
- ASEAN Senior Economic Official Meeting (SEOM)
- ASEAN Consultative Committee on Standards and Quality (ACCSQ)

**WG 1**
Working Group on Standards and Mutual Recognition Arrangements (MRAS)

**WG 2**
Working Group on Accreditation and Conformity Assessment

**WG 3**
Working Group on Legal Metrology

**JSC EE MRA**
Joint Sectoral Committee for ASEAN Sectoral MRA for Electrical and Electronic Equipment

**ACC**
ASEAN Cosmetic Committee

**PPWG**
Pharmaceutical Product Working Group

**PFPWG**
Prepared Foodstuff Product Working Group

**APWG**
Automotive Product Working Group

**TMHSPWG**
Traditional Medicines and Health Supplements Product Working Group

**WBPG**
Wood-Based Product Working Group

**RBPWG**
Rubber-Based Product Working Group

**MDPWG**
Medical Devices Product Working Group

26-Mar-07
Harvard Med. Dev. Congress; International Regulatory Harmonization; M. Gropp March 07
ASEAN Consultative Committee on Standards and Quality Medical Devices Product Working Group

• Mandate from ministers to remove technical barriers to trade, to provide medical industry in ASEAN with a better environment for growth, and to ensure faster access to safe and effective medical devices

• Emphasis on need to coordinate with GHTF and align regional regulatory framework with international practices

• ASEAN objective to promote harmonization of standards

• Accelerating economic integration toward establishment of Asian economic community
Asia-Pacific medical device regional regulatory harmonization initiatives

- GHTF
- PAHO
- AHWP
- APEC
- ACCSQ MDWPG (ASEAN)
- APEC LSIF
- APEC Funded Training Seminars
APEC Life Sciences Innovation Forum

“Capacity building for the harmonization of standards and regulatory practices for bio-medical products and services according to international best practices where the need is most pressing and obstacles are the greatest.”

Source: APEC Life Sciences Innovation Forum:  http://www.apec.org/apec/apec_groups/other_apec_groups/life_sciences.html
Examples of countries/regions developing regulations based on GHTF guidance

• Malaysia (parliamentary bill due in March 2007)
• Hong Kong SAR (already implemented and ongoing)
• Saudi Arabia (early stage)
• South Africa (early stage)
• India (?)
Industry concerns

• “Highest common denominator” of regulatory requirements?

• Risk of being shut out of all markets due to non-compliance in one?

• Can all governments developing regulations devote adequate resources?

• Regulatory redundancy or repetition?
Conclusions

• Regional and international regulatory harmonization supports global medical device product development and clinical trial strategies
  • Moving at differing speeds
  • Some early “successes”

• Regional harmonization initiatives underway
  • Opportunity for prospective harmonization
  • Need sustained political support and funding
  • Coordination would be helpful

• Initiatives can promote timely access of patients, clinicians, and health care systems to safe and effective medical device technology
Conclusions

• In practice, requirements and practices often do not yet “feel” harmonized
• What does “implementation” look like in practice?
• How to define “success”?
• Much more to be done
• Requires joint efforts of regulators and industry
GHTF Vision

Enhancing the health of the public worldwide and facilitating innovation by harmonizing the global regulatory environment