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Benefits of Harmonization

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ASIAN HARMONIZATION WORKING PARTY

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Harmonization Efforts in Asia

- Asian Harmonization Working Party (AHWP)
- Global Harmonization Task Force (GHTF)
- Association of Southeast Asian Nations (ASEAN)
- Asia Pacific Economic Cooperation (APEC)

Asian Harmonization Working Party (AHWP) Overview

- AHWP was formed around 1996-97 composed of an informal group of experts from medical device regulatory authorities and the medical device industry.
- Main Objectives:
  - Forge a common direction for the harmonization of medical device regulation in Asia.
  - Encourage understanding on the benefits of harmonization and facilitate a linkage with the GHTF.
  - Seek to establish AHWP as a formal regional grouping under the GHTF
  - Provide a forum for discussion and training

AHWP (con't)

- Member economies include:

Brunei Darussalam	Korea	Thailand
Cambodia	Lao PDR	Vietnam
Chinese Taipei	Malaysia	
Hong Kong SAR	People's Republic of China	
India	Philippines	
Indonesia	Singapore	
Kingdom of Saudi Arabia	South Africa	

Purpose:

"…to study and recommend ways to harmonize regulation in the Asian region with global trends and to work in coordination with the GHTF and Asia Pacific Economic Cooperation (APEC)…"

Global Harmonization Task Force (GHTF) Overview

- Founded in 1992 by Canada, EU, Japan, US. Australia joined in 1993.
- Informal grouping of medical device regulators and industry
- 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.."
- "…accomplished via the publication and dissemination of harmonized guidance documents on basic regulatory practices"

GHTF (con't)

- 2006 – Membership was expanded to 3 liaison body members: AHWP, ISO, IEC
- Steering Committee and Five Study Groups
  - Study Group 1: Pre-market Evaluations
  - Study Group 2: Post-market Surveillance/Vigilance
  - Study Group 3: Quality Systems
  - Study Group 4: Auditing
  - Study Group 5: Clinical Safety/Performance

GHTF- Access to documents

Association of Southeast Asian Nations (ASEAN) Overview

- Political and economic organization founded in 1967 by:
  - Philippines, Malaysia, Thailand, Indonesia, Singapore
  - and now includes Brunei Darussalam, Cambodia, Lao PDR, Myanmar, Vietnam

ASEAN (con't)

- ASEAN Consultative Committee on Standards and Quality (ACCSQ) Medical Device Product Working Group (MDPWG)
  - remove technical barriers to trade, provide ASEAN medical industry a better environment for growth, ensure faster access to safe and effective medical devices
  - emphasis on coordination with GHTF with alignment of regional regulatory framework with international practices
  - promote harmonization of standards
  - accelerate economic integration toward establishment of Asian economic community

Asia Pacific Economic Cooperation (APEC) Overview

- Founded in 1989 as a group of Pacific Rim countries who meet with the purpose of improving economic and political ties
- 21 member economies
- Funds regional regulatory training meetings between industry and government regulators

  - Bangkok, June 2005

  - Santiago de Chile, May 2006

  – Kuala Lumpur, March 2008 as a joint meeting with AHWP

Harmonization is….

- **Harmonization**: " to bring into agreement or harmony"
- **Harmony**: "agreement in feeling or opinion; accord"
  American Heritage College Dictionary, 3rd Ed., 2000

- **Medical device harmonization**: "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.

GHTF, http://www.ghtf.org/about/index.html

Key Facts

- Great changes in the world economy
  - slower growth in US, EU, Japan and robust growth in developing countries, sustained and rapid growth in China and India with continuing high growth potential
  - Desire of developing economies to ensure safety and performance of products brought to their markets
  - depreciation of the USD with strong adverse effects on economic growth
  - growing pricing pressures
  - medical devices are one of the fastest growing industries
  - Rapid development of new technologies

Key Facts (con't)

- "Market trends prompt the need for better operating model"…
  - "traditional lines of business, technology, and competition are blurring
  - international market is BIG…and getting bigger
  - definition of customers is changing
  - regulatory scrutiny is increasing"

Medical Device & Diagnostic Industry, January 2008

Key Facts (con't)

- Increasing regulatory pressures on government and industry – scarcity of resources, both human and financial
- Demographic trends are driving fundamental changes in the global economy

What Role can Regulatory Harmonization Play ????

- Reduce time to market by:
  - eliminating undue or perhaps unjustified country-specific requirements
  - providing transparent requirements

Which simplifies market access and expedites patient access to new and innovative technologies.

Role of Harmonization (con't)

- Reduce costs by:
  - establishing uniform international regulatory systems and requirements
  - reducing unwarranted, often contradictory regulatory requirements and redundant applications of similar requirements and can lead to different product definition in various geographies, further complicating follow up and comparison of data on safety issues.

Which reduces resources and the complexity needed to meet local requirements and improves the utilization of already stretched and limited human and financial resources.

Role of Harmonization (con't)

- Improve government efficiencies by:
  - facilitating cooperation among regulators and industry in conducting regulatory activities such as common audits, submission requirements, PMS procedures, acceptance and use of international standards, exchange of safety information which can be leveraged on experience gained over time.

Role of Harmonization (con't)

- Facilitate trade and expand market access by:
  - creating common requirements for addressing product life cycle (development, manufacture, placing on the market, post-market surveillance)

Which reduces the burden, complexity, and unpredictability for gaining market clearance.

Role of Harmonization (con't)

- Enhancement of public health protection by:
  - establishing common and transparent pre-market evaluation, post-market surveillance, uniform quality systems with similar audit criteria, common clinical safety/performance

Which provides increased product safety and efficacy thereby promoting public health and ensuring consumer confidence.

Challenges to Harmonization

- Diversity in culture, language, politics, economy, race, religion
- Differing regulatory capacity, expertise, infrastructure, finance
- Varied collection of regulatory systems, differences in philosophy
- Rising and varied expectations of medical technology

Challenges (con't)

- Historical issues – retention of sovereignty, trust and confidence in decisions/assessments from various regulators
- Difficulties in stakeholders to reach consensus on harmonization efforts
- Overall complexity of the products and the marketplace
- Sheer magnitude in the number of countries that are currently regulated, modifying regulations, developing new regulations

What if we don't harmonize ???

- Continued and escalating divergence between statutory regulatory systems leading to:
  - Incomplete regulations, lack of implementing guidelines
  - Confounding regulatory requirements in the following areas:
    - Pre-market evaluation (product classification, submissions, review, clinical protocols/expectations, approval times)
    - use of standards
    - quality system requirements
    - Audits
    - vigilance: definition, reporting, decision-making

What if we don't harmonize ??? (con't)

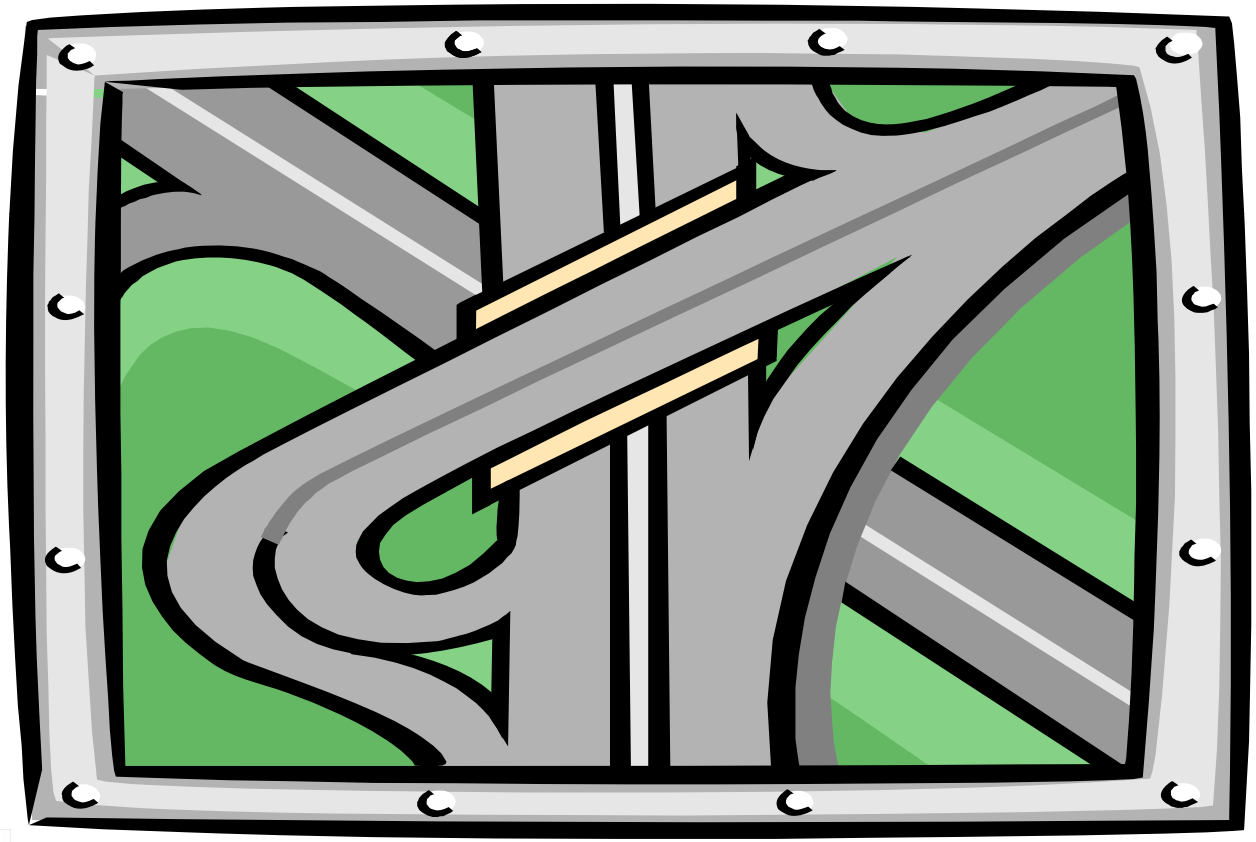
- Lack of or inability to leverage information sharing
- Lack of common requirements/processes for handling new, innovative devices

Risk of Not Harmonizing (con't)

- Unpredictable environment due to development of unclear regulations and control of the system
- Continued rise in cost of medical therapies
- Uneven playing field leading to market access barriers
- Delayed or absent access to innovative technology
- Reduced, impaired access to important, life-saving devices

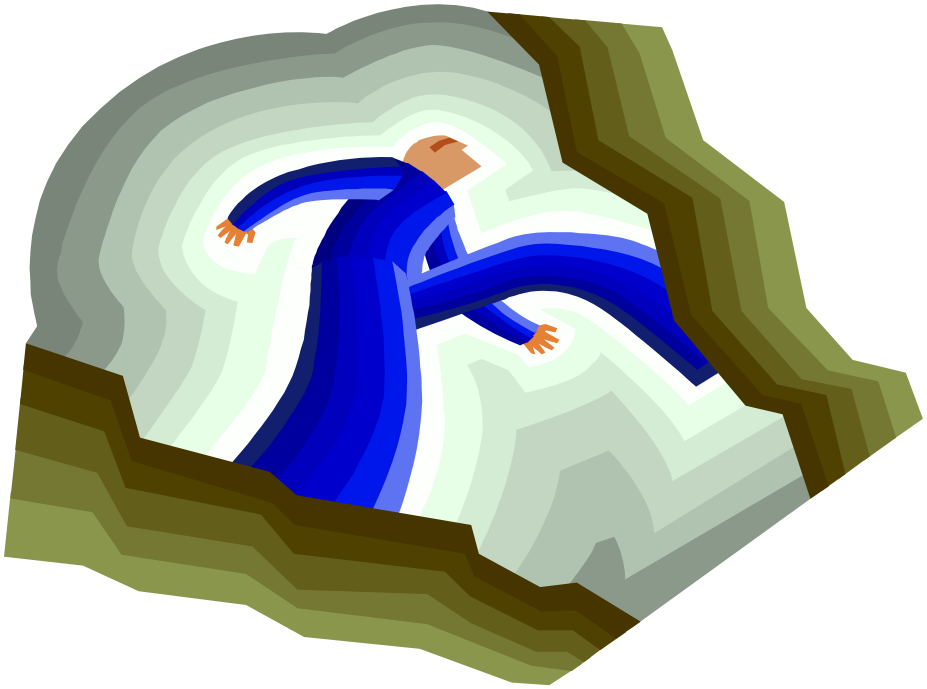
"If you do not change direction, you may end up where you are heading."

Lao Tzu



- Golden Opportunity for Regulators and Industry to build an effective harmonized pre-market approval and post-market vigilance systems that will:
  - Facilitate exchange of information by speaking the same “technical language” and having common and comparable standards and data
  - Reduce redundancy and optimize resources
  - Reduce overall cost of medical therapies to patients around the world
  - Deliver medical therapies that are safe and effective in saving life

“The journey of a thousand miles begins with one step.”
Lao Tzu



- Embrace the next few days of workshop topics
- Share and participate in the discussions
- Meet your colleagues, become acquainted
- BECOME INVOLVED


Thank you !