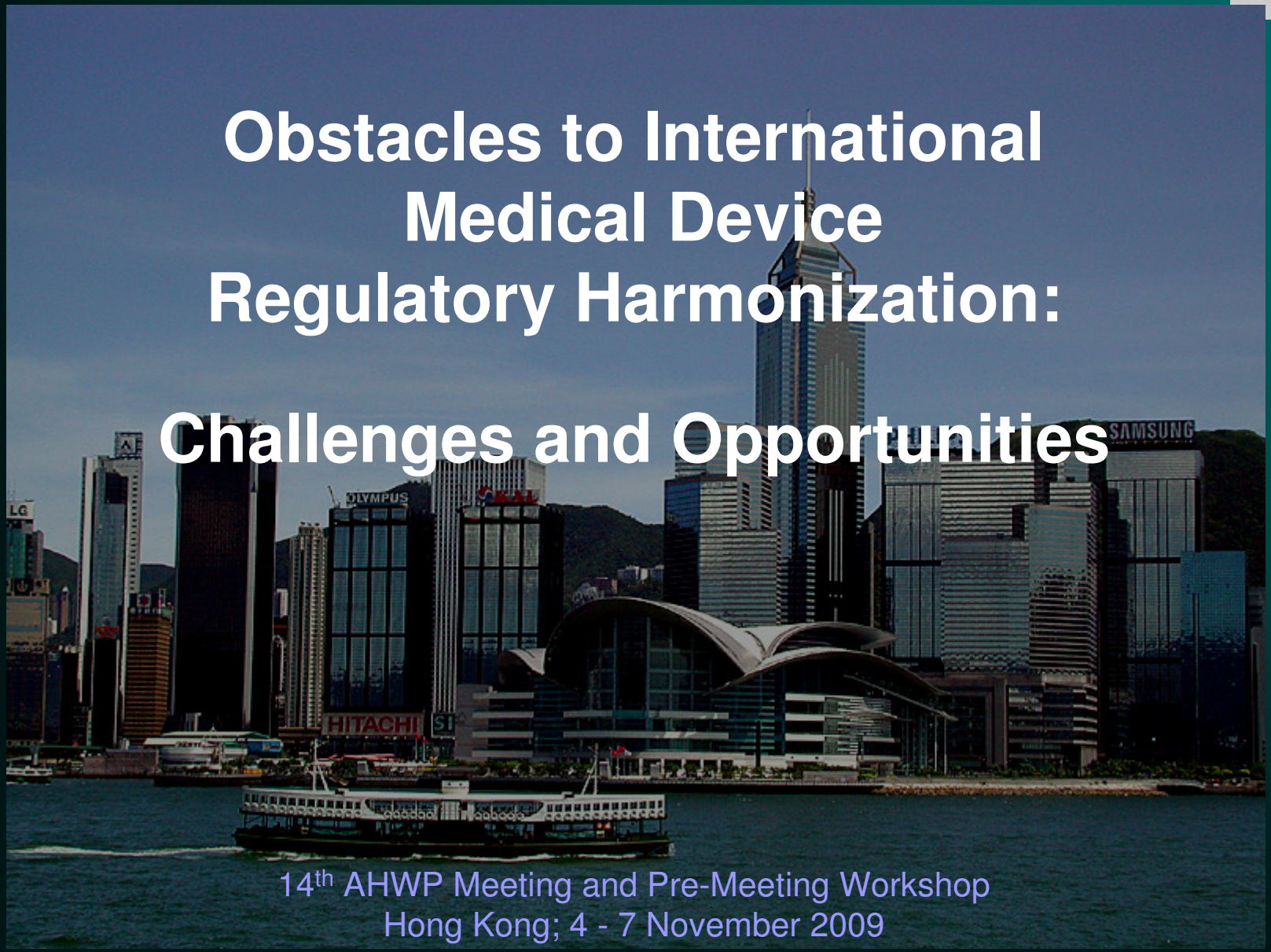

Obstacles to International Medical Device Regulatory Harmonization:

Challenges and Opportunities

14th AHWP Meeting and Pre-Meeting Workshop
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M. Gropp; Medtronic, Inc., Minneapolis, USA

Introduction

- Personal reflections
- General observations
  - No specific examples presented
  - Not to blame or criticize
- How to move international harmonization from theory to practice?
- Obstacles → opportunities?
- More questions than answers

GHTF Vision

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

GHTF Strategic Direction – Goals (1)

Emerging regulatory challenges

- GHTF will encourage and support timely identification of opportunities to promote **regulatory convergence** in addressing regulatory challenges including those of emerging public health risks and new medical technologies
- GHTF will implement a process to identify these new risks and technologies in order to achieve regulatory convergence in their management

Source: *GHTF Steering Committee; Lubeck, June 2006 [emphasis added]*

GHTF Strategic Direction – Goals (2)

Implementing guidance documents

- GHTF will encourage the adoption of timely and clear guidance suitable for **implementation** in national/regional regulatory systems

Source: *GHTF Steering Committee; Lubeck, June 2006 [emphasis added]*

GHTF Strategic Direction – Goals (3)

Mutual acceptance by regulators

- GHTF will seek to evolve beyond convergence of regulatory requirements to embrace **mutual acceptance** of common data submissions, pre-market conformity assessment (including clinical evidence) processes, quality systems, quality systems auditing results, and a broad sharing of post-marketing experience
- The objective will be to allow presentation of data that are acceptable in principle to relevant authorities as the basis for meeting regulatory requirements

Source: *GHTF Steering Committee; Lubeck, June 2006 [emphasis added]*

GHTF Strategic Direction – Goals (4)

Evolving regulatory systems

- GHTF Steering Committee will support and advocate the **adoption** of the global regulatory model in their own systems and those of other countries/regions

Source: *GHTF Steering Committee; Lubeck, June 2006 [emphasis added]*

GHTF Strategic Direction – Goals (5)

Communications

- GHTF Steering Committee will develop, implement and monitor a comprehensive communications strategy

Source: *GHTF Steering Committee; Lubeck, June 2006*

GHTF Strategic Direction – Goals (6)

Organization/infrastructure

- GHTF members will seek to establish an affordable, enduring apparatus for managing and advocating the GHTF business agenda

Source: *GHTF Steering Committee; Lubeck, June 2006*

AHWP Purpose

To study and recommend ways to harmonize medical device 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*

AHWP Purpose

AHWP will strive to:

- Examine the use of quality system requirements around the world and prospects for **adopting a quality system standard** based on internationally recognized and accepted quality system standard for medical devices
- Work toward building a common regulatory consensus based on **acceptance of international standards** as the chief means of ensuring product safety and assurance
- Move toward **recognition of a common audit** that can be accepted throughout the Asian region
- Work toward a **harmonized system of medical device vigilance reporting** for adoption within the region and information sharing …..

Source: *AHWP: Terms of Reference [emphasis added]*

Challenges

- Apparent consensus that harmonization and regulatory convergence are desirable
- Gap between aspirations and reality?
- Harmonization in requirements and in practice?
- Significant progress has been made, but why not more?
- How does current situation affect technology innovation to address public health needs?

Obstacles

Lack of opportunity

- Convergence depends upon opportunities
  - New regulations under development
  - Regulations under revision
- May require adoption or revision of laws
- Depends upon political/policy recognition of need
- Depends upon political direction to harmonize
- Prospective harmonization easier than retrospective

Obstacles

Lack of political imperative and framework

- At regional or supranational level
- Failure of political commitments to “trickle down” to practical steps

Obstacles

Lack of "joined up" thinking on government policies

- Relationships between medical device regulation and trade, domestic industrial development, infrastructure, innovation and competitiveness policies, and public health needs not always considered

Obstacles

Regulation as protective barrier

- Relationships between medical device regulation and trade and domestic industrial development
- Technical barriers to trade

Obstacles

National 'exceptionalism'

- Belief that national circumstances prevent convergence
- Belief that national population differences justify regulatory differences
- Differences greater than similarities

Obstacles

Medical device regulations based on existing medicines laws and regulations

- May be only existing legal/regulatory framework
- Requirements and administrative requirements often not appropriate for, and do not accommodate, medical devices
- Training and expertise of regulators not in specialized disciplines needed for medical devices

Obstacles

Adopting harmonized guidance individually, without reference to other guidance documents

- Inter-connected elements of GHTF regulatory model
- Sequence of implementation

Obstacles

Reliance upon product testing

- Insufficient confidence in manufacturer's design controls and quality management systems
- Carryover from other industry sectors
- Desire for a single standard to encompass all aspects of a medical device (as in pharmacopeia monographs for medicines)
- Vested interests of testing bodies

Obstacles

Lack of established conformity assessment resources

- No or inadequate test houses or conformity assessment bodies to assist manufacturers in design verification and demonstrating conformity
- Lack of accreditation standards and/or mechanisms
- Lack of national competent authority oversight

Obstacles

Lack of standards

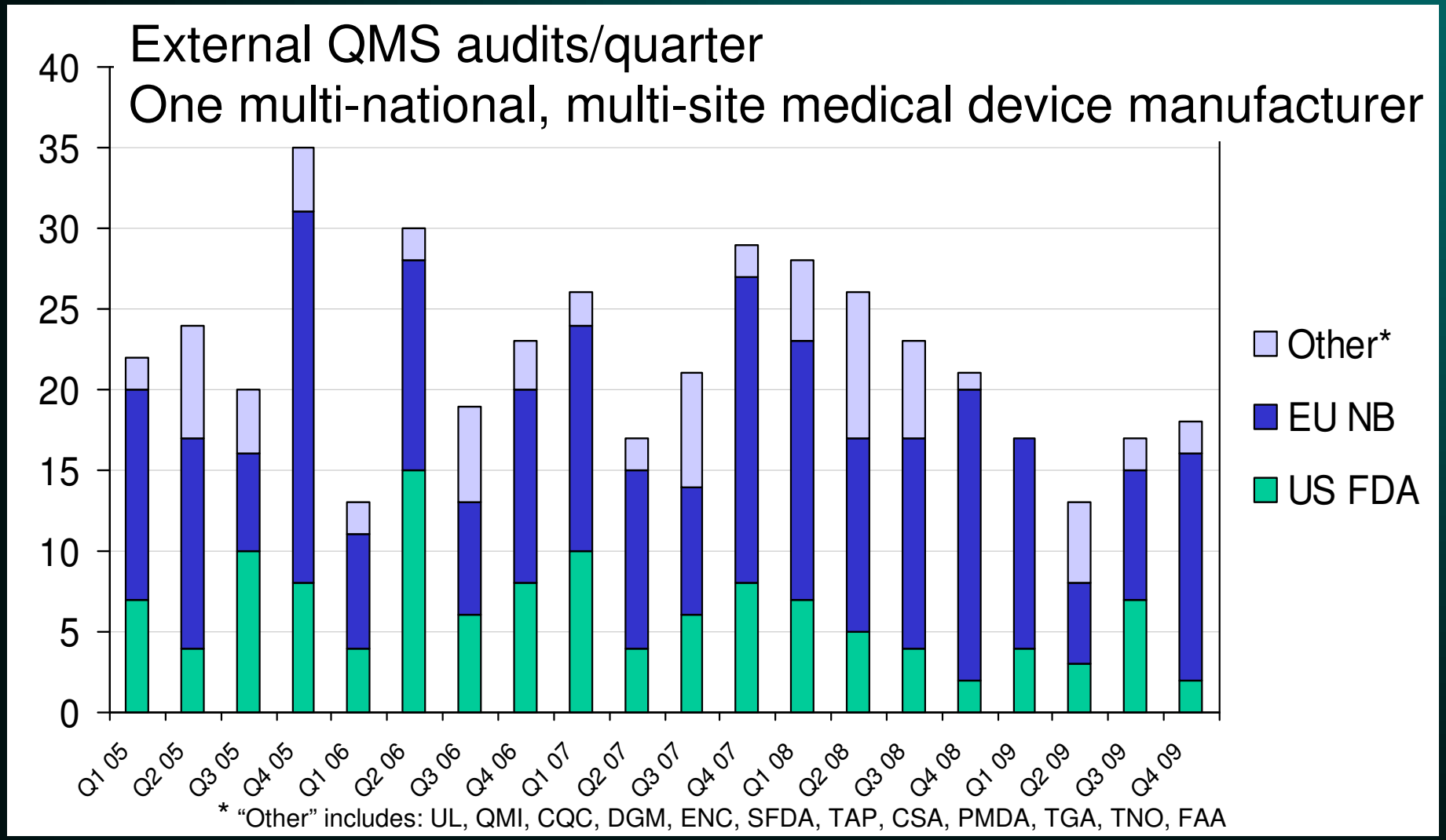
- Lack of voluntary standards to which manufacturer may refer for demonstrating conformity with harmonized regulatory requirements
- Lack of national standards body or committees in medical devices field
- National standards not consistent with international standards
- National deviations to international standards

Obstacles

Reluctance to accept results of conformity assessment done elsewhere

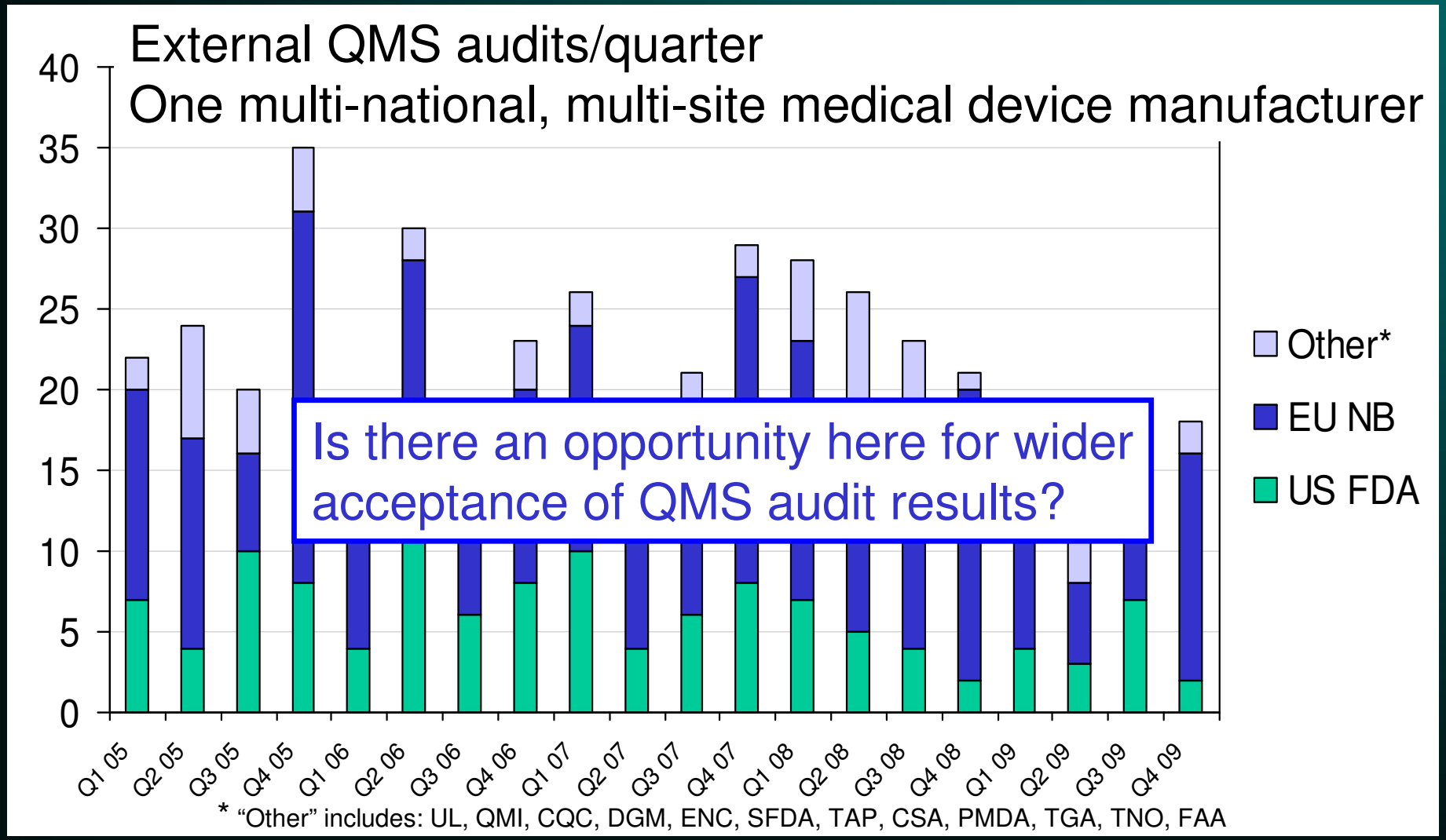
- Balance between need for local pre-market review vs. local market surveillance and oversight?
- Can such results be generally accepted as evidence of substantial conformity with national requirements?

Mutual acceptance by regulators



Source: Medtronic, Inc.

Mutual acceptance by regulators



Obstacles

Lack of institutional support for harmonization forums

- Permanent secretariat
- Political “standing” in governmental and quasi-governmental forums
- Ongoing support for professional training and sharing of experience, learning, and successes
- Institutional memory
- Funding

Obstacles

Different legal/administrative systems

- Not specific to medical devices
- Process of developing regulations
- Openness, transparency, opportunities for involvement of stakeholders, public comment
- Regulatory impact assessment

Obstacles

Different speeds, capacities, and starting points

- Within a region, some economies have well-established regulations and well-resourced regulators, others do not
- Differences in local industry composition
- Differing government regulatory and public health priorities
- Is multi-speed harmonization within a regional grouping of economies possible?

Obstacles

Practical difficulties

- Lack of time and money
- Conflicting priorities
- Linguistic difficulties
- Lack of expertise and training
- Lack of experience with other systems
- Lack of awareness of developments in GHTF, AHWP, etc.

Obstacles

Practical difficulties

- Rotation and turnover of staff
- Lack of enabling tools, e.g., global nomenclature system or vigilance information systems
- Insufficient exchange of information and coordination amongst harmonization forums
- Administrative inertia

Where to now?

- Which obstacles are under our control or influence?
- What is required to influence them?
- How to define “success”?
  - Near term?
  - Longer term?
- How to “leverage” experience and expertise?
- Opportunities for “pooling of competence”?

Where to now?

- How to preserve national responsibility for protection of public health and promote convergence and efficiency of regulatory requirements and practices?
- What are the opportunities for innovation in regulatory practices?

GHTF Vision

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