INTERNATIONAL TRADE ADMINISTRATION

Global Medical Devices Regulatory Harmonization Training – Coordination of AHWP and APEC AHWP

AHWP Annual Meeting, Hong Kong

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Presentation Outline

- Global Medical Devices Regulatory Training Goals and Objectives
- Past APEC and GHTF Training Programs
- Results of Past Training
- Future Training Plans
- Summary and Conclusion

Global Medical Devices Regulatory Harmonization Training Goals and Objectives

- To educate regulators from non-founding member GHTF countries economies in the process of developing or updating regulatory systems

- To provide background and conceptual understanding of the how the GHTF founding member economies regulate and monitor medical devices already on the market

- To provide an understanding of the guidance documents of the five GHTF Study Groups

GHTF Training Benefits

- GHTF training programs are coordinated closely with the Asian Harmonization Working Party, the Latin American Harmonization Working Party, and the Pan American Health Organization (PAHO)
- Regulators benefit from a harmonized global medical device regulatory system because it eliminates redundant reviews, creates an opportunity to share information on product safety, and results in a more efficient regulatory regime

- Industry benefits from a harmonized medical device regulatory system because it eliminates redundant requirements that do not contribute to safety
- The net result is improved trade in medical devices, and safer products for consumers

Past GHTF Regulatory Harmonization Training Events

- March 1999 – APEC Funded Seminar Singapore
- May 2001 – APEC Funded Seminar Singapore
- June 2005 – APEC Funded Seminar Bangkok, Thailand
- May 2006 – APEC Funded Seminar Santiago, Chile
- October 2007 – GHTF Organized Latin American Seminar, Washington, D.C.
- February 2008 – APEC Funded Seminar KL, Malaysia
- March 2009 – ASEAN Seminar Penang, Malaysia
- May 2009 – APEC Funded Seminar Toronto, Canada
- September 2009 – APEC Funded Asia Delegation Visit to Australia
- September 2009 – USDOC Funded Seminar Brasilia, Brazil

GHTF Regulatory Events: Results

Participants in past GHTF harmonization training have reported that:

- Seminars useful to develop strategies to advance the use of GHTF guidance documents
- Participating economies have moved toward the STED model
- ASEAN countries likely to continue adopting GHTF guidance documents in the next three to ten years
- Participating countries have requested support in implementation of new or revised regulatory regimes

GHTF Regulatory Training Results

- Attendees have expressed an interest in future regional training seminars or held in conjunction with future GHTF conferences
- The following economies have revised or are in the process of revising their medical device regulatory regimes based on GHTF principles:
  - Malaysia
  - Singapore
  - Hong Kong
  - Several other ASEAN countries as part of ASEAN ACCSQ Medical Device Products Working Group

GHTF Training: Topics Covered at Bangkok

- Study Group 1
  - Definition of a Medical Device
  - Essential Principles of Safety and Performance of Medical Devices
  - Summary Technical Documentation
  - Conformity Assessment
  - *In Vitro* Diagnostics and Global Harmonization
  - Principles of Medical Device Classification
  - Role of Standards in Assessment of Medical Devices
- Study Group 2
  - Adverse Event Reporting
  - Reporting Timeframes
  - Vigilance Systems: Some Practical Issues

GHTF Training: Topics

Presentations (continued)

- Study Group 3
  - ISO 13485: Overview
  - Quality Management Systems: History and Evolution
  - Implementation of Risk Management Principles
  - Introduction to Design Verification and Validation
  - FDA Export Certificates
  - Process Validation Guidance
  - Quality Management Systems: History and Evolution

GHTF Training: Topics Covered

Presentations (continued)

- Study Group 4
  - Auditing and Overview of GHTF
  - Plan-Do-Check-Act Case Study
- Special Presentations
  - New Medical Technologies: Challenges for Regulators
  - Essential Principles of Safety and Performance of Medical Devices
  - Medical Device Regulatory Global Crystal Ball Forecast
  - GHTF Vision
  - Clinical Evidence (Study Group 5)

GHTF Training:

Reported challenges to implementing GHTF Guidance Documents (based on attendee feedback)

- Different levels of staff competency and capacity as well as lack of coordination among government sectors make harmonization difficult
- Considerable regulation changes present challenges for developing regulatory systems. Medical device industry too diverse for "one size fits all" legislation
- Local industries lack knowledge in understanding GHTF regulatory requirements
- Economies have different reporting requirements for adverse events
- Industry concerned that competent authorities overreact at adverse events

GHTF Training:

Reported challenges to implementing GHTF Guidance Documents (based on attendee feedback) (continued)

- Industry concerned that auditors lack competence or are better trained for GMP drug reviews: continuous education needed,
- Divergent risk-based classification in different countries poses problems
- Reporting requirements not always seen as related to demonstration of safety of product
- Global Medical Device Nomenclature not interpreted identically in all countries
- Economies modify Summary Technical Documentation, so industry must customize dossiers
- Auditors not ready to change from local GMP requirements to GHTF Quality Systems model

Future GHTF Training Plans

- GHTF Ad Hoc Training Committee, Chairperson Jan Welch, US FDA – Possible Future Partners for Training GHTF
- September 2010 – APEC Funded Latin American Delegation to the U.S. and Canada
- Possible Follow-up to March 2009 ASEAN Workshop
- Possible Follow-up to September 2009 Brazil Workshop
- Possible future APEC Regulatory Harmonization Project with Asia and Latin American Seminars

Summary and Conclusion

- During my presentation I covered the following
  - GHTF Training Goals and Objectives
  - Past APEC and GHTF Training Programs
  - Results of Past Training
  - Future Training Plans

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