



INTERNATIONAL
TRADE
ADMINISTRATION

Global Medical Device Regulation Harmonization Training

Presented by:

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Presentation Outline

- Training Goals and Objectives
- Past Global Medical Device Regulation Harmonization Training
- Results of Past Training
- Future Training Plans
- Summary and Conclusion

Training Goals and Objectives

- To educate regulators from 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

Harmonization Training is Truly Global

- Training programs coordinated closely with the Asian Harmonization Working Party, the Latin American Harmonization Working Party, and the Pan American Health Organization (PAHO)
- *All* economies welcome to participate in GHTF regional harmonization training programs

Harmonization Training Benefits

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

Medical Device Regulation Harmonization Training Events

- **May 2000: APEC – Funded Seminar on Harmonization of Medical Device Regulation: Singapore**
- **May 2002: APEC – Funded Seminar on Harmonization of Medical Device Regulation: Singapore**
- **June 2005: APEC – Funded Seminar on Harmonization of Medical Device Regulation: Bangkok, Thailand**
- **May, 2006: APEC – Funded Seminar on Harmonization of Medical Device Regulation: Santiago, Chile**

Harmonization Training Events: Results

Participating economies in 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 economies likely to continue adopting GHTF guidance documents in the next three to ten years
- Participating economies have requested support in implementation

Harmonization Training Events: Results

Participating economies in GHTF harmonization training have reported that: (continued)

- 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
 - Other economies doing so as part of ASEAN ACCSQ MDPWG

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

Coverage of 2005/2006 Training Program

- 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

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

Presentations (continued)

- Study Group 3
 - ISO 13485: 2003 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

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

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)

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

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

- 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: mistrust between regulators and industry a problem

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

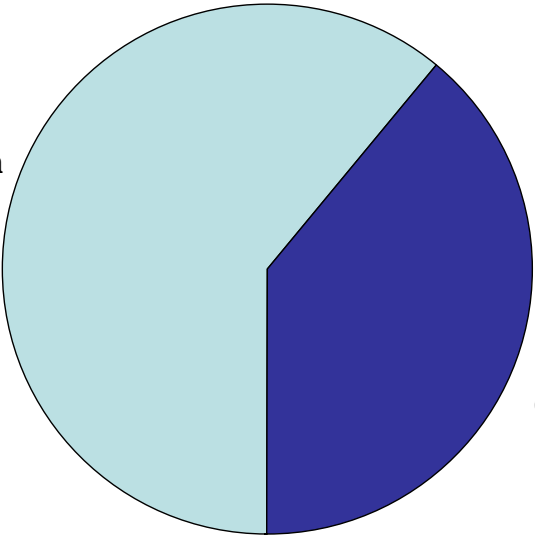
Reported challenges to implementing GHTF Guidance Documents (based on attendee evaluations) (continued)

- 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 economies
- Economies modify Summary Technical Documentation, so industry must customize dossiers
- Auditors not ready to change from local GMP requirements to GHTF Quality Systems model

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

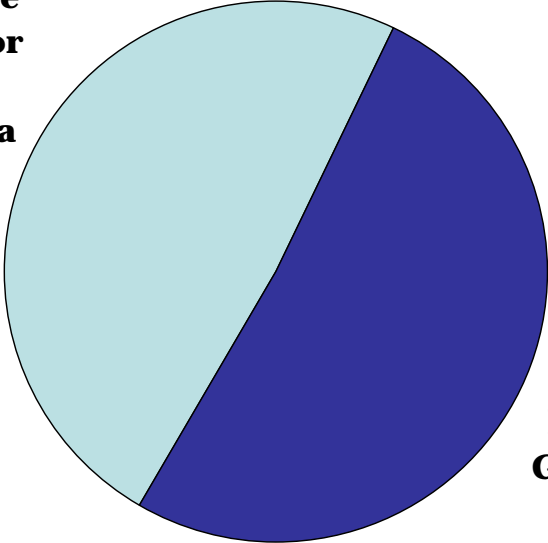
Preferences for future training

**Two
Separate
Regional
Sessions
(Asia/Latin
America)
61%**



Bangkok 2005

**A Totally
Separate
Event for
Latin
America
49%**

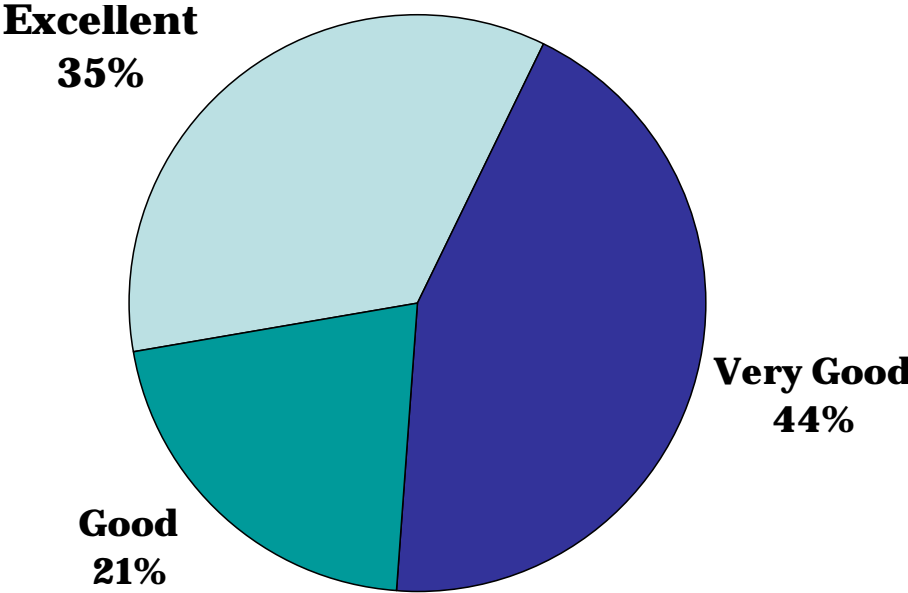


**Training
Linked to a
Global GHTF
Meeting
51%**

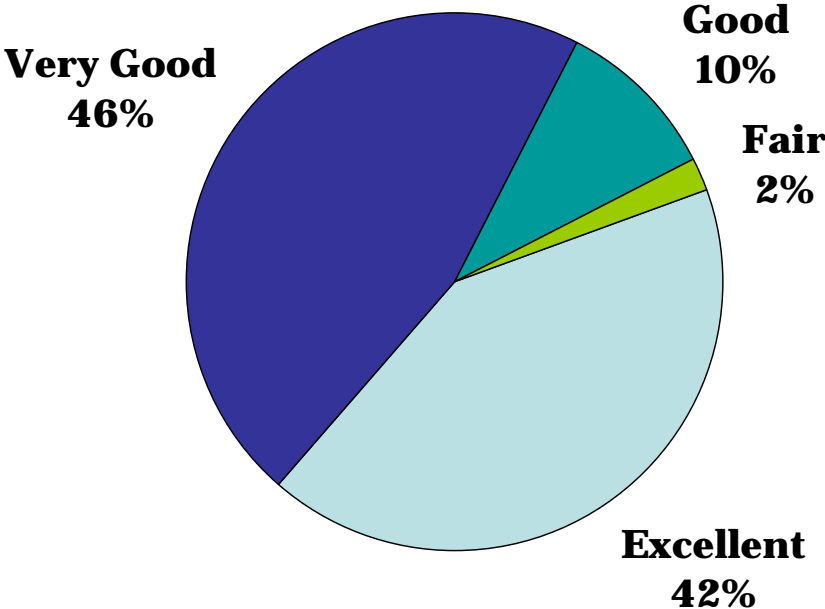
Santiago 2006

Harmonization Training: A Closer Look at Bangkok 2005 and Santiago 2006

Evaluation responses



Bangkok 2005



Santiago 2006

Future Harmonization Training Plans

- October 2007 Latin America Training in Washington, D.C., in coordination with GHTF Annual Meeting, in cooperation with U.S. FDA and Industry
- The U.S. Department of Commerce, in cooperation with U.S. FDA and GHTF, has received approval for APEC funding for training programs to be implemented during 2008 and 2009
 - Kuala Lumpur: March, 2008 in coordination with GHTF's Steering Committee Meeting
 - Mexico City: 2009 in coordination with GHTF Steering Committee Meeting

Future Harmonization Training Plans

- This round of training would include AHWP and LAHWP delegation visits to GHTF founding member economies
 - The purpose of the delegation visits is to familiarize participants with developed medical device regulatory regimes, and would include meetings with regulators as well as visits to medical device manufacturing facilities

Summary and Conclusion

- During my presentation I covered the following
 - Harmonization training goals and objectives
 - Past harmonization training
 - Results of past training
 - Future Training plans



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