

# GHTF Training Initiative

GHTF Steering Committee

October 2007



# Objective of Training Initiative

## ■ To educate

- Medical device regulatory authorities
- Industry members
- Conformity assessment bodies

- in any interested country or region on the guidance documents developed by the GHTF and on the overall model of harmonized medical device regulation embodied in those documents



# Possible Curriculum Topics

- Overview of a “Global Regulatory Model”
  - The need for regulations for devices
  - Regulatory options to regulate devices
- Organizational and procedural documents
- GHTF Study Group documents
  - Translated documents as appropriate
- Implementing a regulatory system
- Special topic/training: National Competent Authority Reporting (NCAR) Program



# The Trainers

- GHTF Study Group members
  - Current or recent members
- GHTF Steering Committee members
  - As appropriate
- The future: train-the trainers programs



# Where and when will GHTF Train?

- Collaboration with the Department of Commerce: APEC initiatives
  - Most recent training in Chile, prior in Bangkok
  - Training planned associated with Malaysia SC meeting in March 2008
- Often paired with GHTF Plenary and Conference or with SG or SC meetings
  - October 2007 year, training with a focus on Latin American region



# Resources for Training

- APEC and the Department of Commerce
- GHTF considering working with partners with education as their mission
- General support will come from registration for training

