

# GHTF Conference 2006

Welcome to Lübeck

Maurice Wagner, Vice Chairman GHTF  
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# Study Group 1 (SG1)

- Mandate
  - a) Comparing existing **medical device regulatory systems** around the world
  - b) Isolating the elements / principles that are suitable for harmonization and those that may present obstacles to uniform regulations
  - c) Developing a standardized format for pre-market submissions and harmonized product labelling requirements.
- Study Group Details

Number of participants: 16, + 7 IVD experts



# Study group 2 (SG2)

- Mandate
  - a) Reviewing current adverse event reporting, post-market surveillance and other forms of **vigilance for medical devices**
  - b) Performing an analysis of different requirements amongst countries with developed device regulatory systems

with a view to harmonizing data collection and reporting systems
- Study Group Details

Number of participants: 17



# Study Group 3 (SG3)

- Mandate

Examining existing **quality system requirements** in countries having developed device regulatory systems and identifying areas suitable for harmonization.

- Study Group Details

Number of participants: 12



# Study Group 4 (SG4)

- Mandate

Examining **quality system auditing practices** (initially among the founding members of the GHTF) and developing guidance documents laying harmonized principles for the external conformity assessment auditing process.

- Study Group Details

Number of participants: 18



# Study Group 5 (SG5)

- Mandate

- **Promoting convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices.**
- Harmonized definitions for commonly used terms (clinical investigation, clinical data, clinical evaluation and **clinical evidence**)
- Harmonized guidance on the content and format for clinical investigation reports and on **how to conduct and document a clinical evaluation**

- Study Group Details

Number of participants: 16, + 3 associate members

