Global Harmonization of Medical Device Regulation: Accomplishments, Challenges and Opportunities

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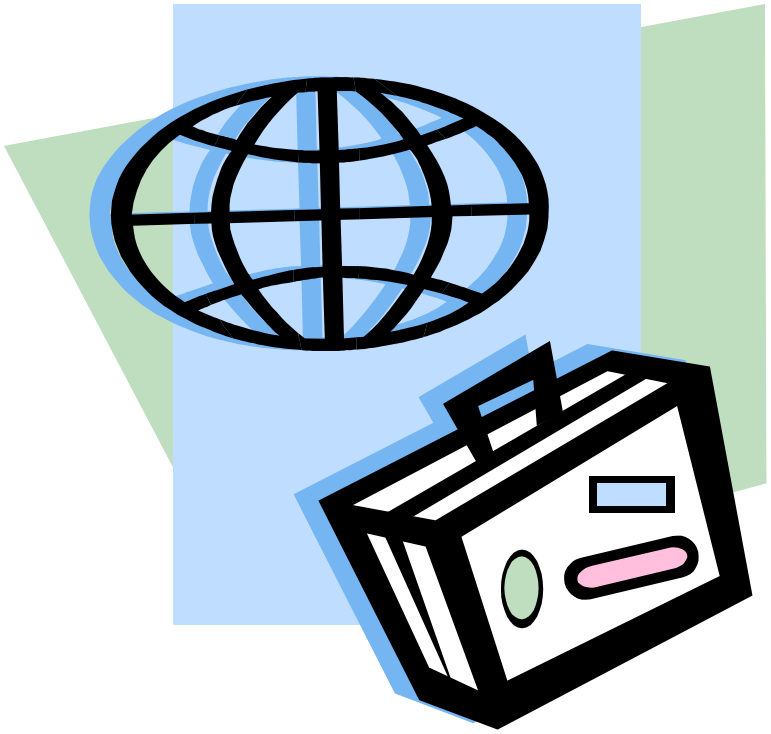
Accomplishments to Date

- Forum for open discussion
- Development of harmonized guidance
- Interaction with other organizations
- Education for nations with emerging systems
- Emerging technologies and related issues



GHTF Challenges

- Differing regulatory paradigms
- Maturity of systems varies
- Significant cultural differences
- Incorporating non-binding “guidance” into legislation and/or regulation difficult for FDA in short time period
- When to emphasize emerging issues

Specific Challenges

- Premarket authorization
  - Essential principles conformance vs. review
- Postmarket surveillance
  - Mature system in the US many reports vs. "case study" approach
- Quality Systems
  - Incorporating risk management
- Auditing
  - Format
  - Depth of Audit

Let's Talk Turkey: Obstacles

- Regulatory organizations must harmonize
  - Agencies have not moved their process
  - Public declaration vs. de facto practice
- Industry must get engaged
  - Summary Technical Evaluation Document not used often: highest or lowest denominator?
  - Few volunteers for joint inspections: concern about impact of one bad inspection?

Taking the Task Force Forward

- Guidance Implementation
  - Audits
  - NCAR
- Organizational Logistics
  - Web redesign
  - More languages
- Expansion
  - Organizational
  - Training and dialogue