Welcome from the GHTF

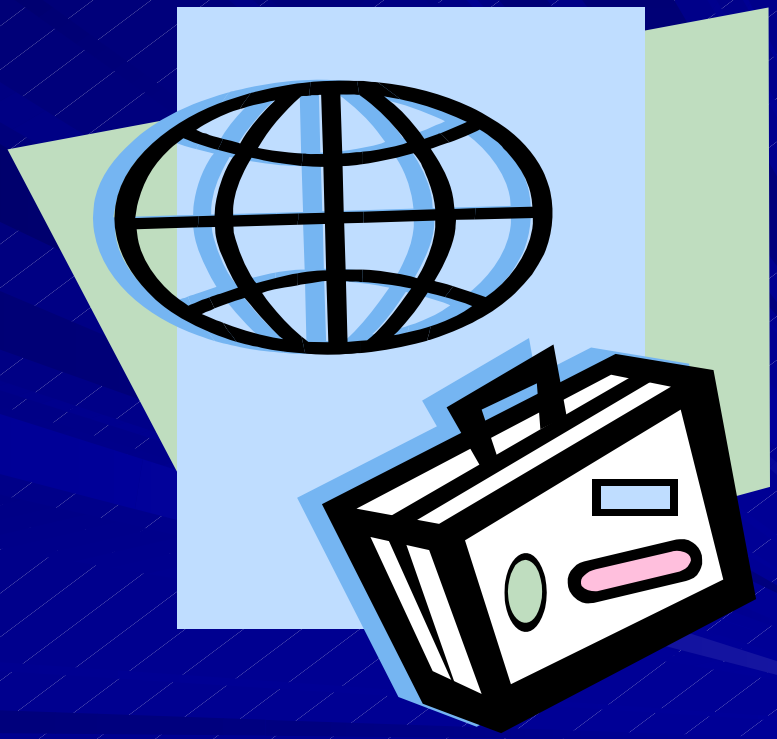
Larry Kessler, Sc.D.
Director, Office of Science and Engineering Laboratories, CDRH, FDA
and Chair, Global Harmonization Task Force

Background

- GHTF in existence for 15 years
- Equal partners between industry and regulators
- Founding members: Australia, Canada, European Union, Japan, United States
- Designed to harmonize existing regulatory systems and to avoid the establishment of new systems with different requirements

Accomplishments to Date

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



Related Recent Developments

- Global Medical Device Nomenclature
  - Gaining steam with more countries adopting
  - US FDA mapping its product code system
  - European Commission to release tender for translation to 21 languages
- Unique Device Identification
  - US will develop a requirement for UDI
  - GHTF hoping to coordinate

Taking the Task Force Forward

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