

GHTF: Goals for the US-Canada Term as Chair 2007 – 2009

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Taking the Task Force Forward



- ▶ Guidance Implementation
- ▶ Organizational Logistics
- ▶ Expansion



Guidance Implementation

- ▶ Time to implement guidance documents
- ▶ Single audits used in multiple jurisdictions!
 - Canada-Australia and Canada-EU agreements
 - FDA-Canada Pilot Multipurpose Audit Program
 - FDA-EU discussions beginning on possible pilot
 - Encourage use of the AP (Accredited Persons)
- ▶ Effective operation of a National Competent Authority Report system



Organizational Logistics

▶ Administrative enhancements

- Narrow objectives, where possible
- Ad hoc groups for specific issues
- Limited timeframes for documents, where possible
- Adhere to procedures, move documents along
- Process of nomination of new items



Expansion

- ▶ Involve other countries, esp. AHWP, PAHO
- ▶ Work with ISO, IEC, others who share the GHTF mission
- ▶ GHTF Training Plan
- ▶ Enhance web site utility and visibility
 - Attempt to create definitive regulatory source
 - Provide for links to translated documents
 - Increased public availability of procedures and documents
- ▶ New topics for discussion, e.g., health product-device products, electronic labeling, medical device software



The Future is Now

- ▶ The GHTF has accomplished much
- ▶ Time to document those accomplishments
- ▶ Let's then build on this foundation and truly move toward the realization of global harmonization





1992 - 2007

Global Harmonization Task Force



Working Towards Harmonization in Medical Device Regulation

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Welcome to the Global Harmonization Task Force Website

The Global Harmonization Task Force was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This is being done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.

A partnership between regulatory authorities and regulated industry, the GHTF is comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The chairmanship is rotated among the Founding Members and presently resides with the United States.



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In the News

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Meetings and Training

- [GHTF 11th Annual Conference](#) - October 3-4, 2007
- [GHTF Steering Committee Reference Guidance on GHTF Training](#)
[PDF](#) (17kb) [Word](#) (36kb)

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SG 1 Proposed Documents

Title	Description	Posted Date	Comments Due:	Comments To:
SG1(PD)/N045R12	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification [Word] [PDF] Request for Comments [Word]	May 14, 2007	September 14, 2007	Ginette Michaud
SG1(PD)/N46/R3	Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices [Word] [PDF]	May 14, 2007	September 14, 2007	Ginette Michaud
SG1(PD)/N045R12 and SG1(PD)/N46R3	Comment Template [Word]	March 16, 2006		

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