GHTF Final Update

17th AHWP – Annual Conference
Taipei International Convention Center
5th November, 2012 (Monday)

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Today's Topic

- Overview of GHTF
  - Purpose, Structure
- Update on GHTF
  - New documents in 2012
  - 22nd SC Tokyo meeting on Oct.29-30, 2012
  - 13th GHTF Tokyo Conference on Oct.31-Nov. 1, 2012
  - GHTF Final Documents and GHTF Regulatory Model
- GHTF Closing Statement

Overview of GHTF

1992-2012

- Began in 1992
- Voluntary forum of medical device regulators and industry
- Five Founding Members
  - Australia, Canada, EU, Japan, USA
- Currently consist of Steering Committee, 5 Study Groups and Ad Hoc Working Group
- Liaison Bodies
  - AHWP, ISO, IEC
- Decisions and actions by consensus
- Chairmanship rotates among the regulatory representatives of the five Founding Members
  - Japan (final chair) : July 2011 – December 2012

The Purpose of the GHTF

- To encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

- The primary way in which this purpose is accomplished is via the publication and dissemination of harmonized documents on basic regulatory practices.
- These documents, which are developed by five different GHTF Study Groups, provide a model for the regulation of medical devices that can then be adopted/implemented by national regulatory authorities.

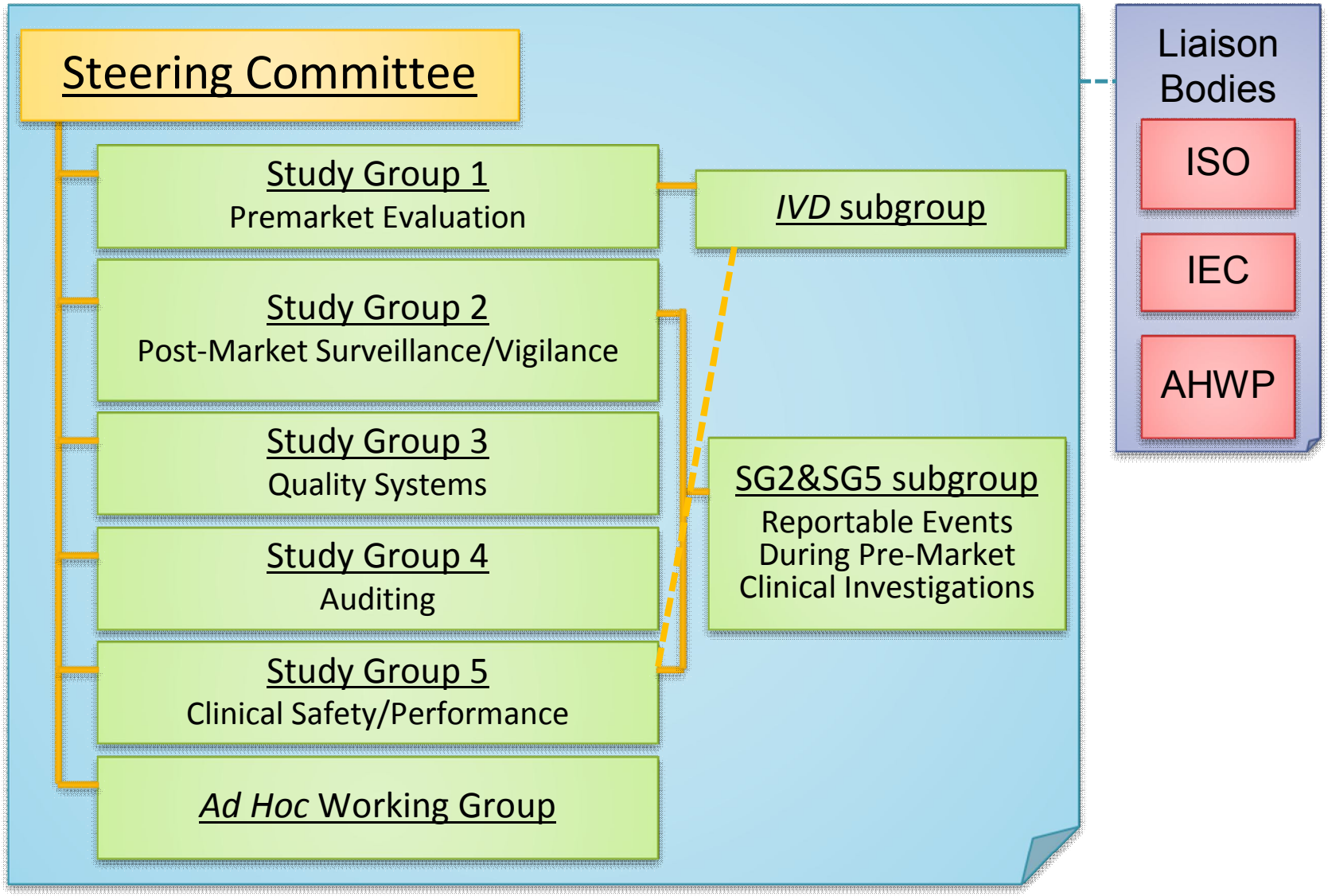
(http://www.ghtf.org/about/)

The Purpose of the GHTF

- Serves as an information exchange forum through which countries with medical device regulatory systems can benefit from the experience of other members.

(http://www.ghtf.org/about/)

GHTF Organizational Structure



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Study Group 1 – New Documents

Title	Description
SG1/N68:2012 *(revision of SG1/N41:2005)*	Essential Principles of Safety and Performance of Medical Devices *(to be published in Nov. 2012)*
SG1/N71:2012 *(revision of SG1/N29:2005)*	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' *(Published on May 23, 2012)*
SG1/N77:2012 *(revision of SG1/N15:2006)*	Principles of Medical Devices Classification *(to be published in Nov. 2012)*
SG1/N78:2012 *(revision of SG1/N40:2006)*	Principles of Conformity Assessment for Medical Devices *(to be published in Nov. 2012)*

Study Group 2 & 3 – New Documents

Title	Description
SG2/N87:2012	XML Schema for the electronic transfer of adverse event data between manufacturers, authorised representatives and National Competent Authorities *(Published on Aug. 1, 2012)*
SG3/N19:2012	Quality management system – Medical Devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange *(to be published in Nov. 2012)*

Note: SG2(PD)/*N111"Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions"* was not approved as Final Document. It was agreed IMDRF would consider this document further as needed.

Study Group 5 – New Documents

Title	Description
SG5/N5:2012	Reportable Events During Pre-Market Clinical Investigations *(Published on Aug. 10, 2012)*
SG5/N6:2012	Clinical Evidence for IVD medical devices – Key Definitions and Concepts *(to be published in Nov. 2012)*
SG5/N7:2012	Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation *(to be published in Nov. 2012)*
SG5/N8:2012	Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices *(to be published in Nov. 2012)*

Steering Committee – New Document

Title	Description
SC/N4:2012 *(Revision of SC/N4:2011)*	Glossary and definition of Terms Used in GHTF Documents *(to be published in Nov. 2012)*

22nd GHTF SC Tokyo Meeting (1)

(Oct 29-30, 2012 - Tokyo, Japan)

- Approval of Final Documents
  - SG1/N68, SG3/N19, SG5/N6-N8
- GHTF Glossary revision : SC/N4 (Edition 2)
- Approval of ANVISA(Brazil) application of NCAR Exchange program
- Update on
  - GHTF Study Groups
  - GMDN (Global Medical Device Nomenclature)
  - IMDRF (International Medical Device Regulators Forum)
  - Founding Members' Regulatory System

22nd GHTF SC Tokyo Meeting (2)

(Oct 29-30, 2012 - Tokyo, Japan)

- GHTF – IMDRF Transition Planning
  - Archiving of GHTF documents and transfer to IMDRF Website
  - Transition of ISO-MOU
  - Recommendation to IMDRF regarding transfer of NCAR program
  - Final Closing Statement

13th GHTF Conference

(Oct 31- Nov 1, 2012 - Tokyo, Japan)

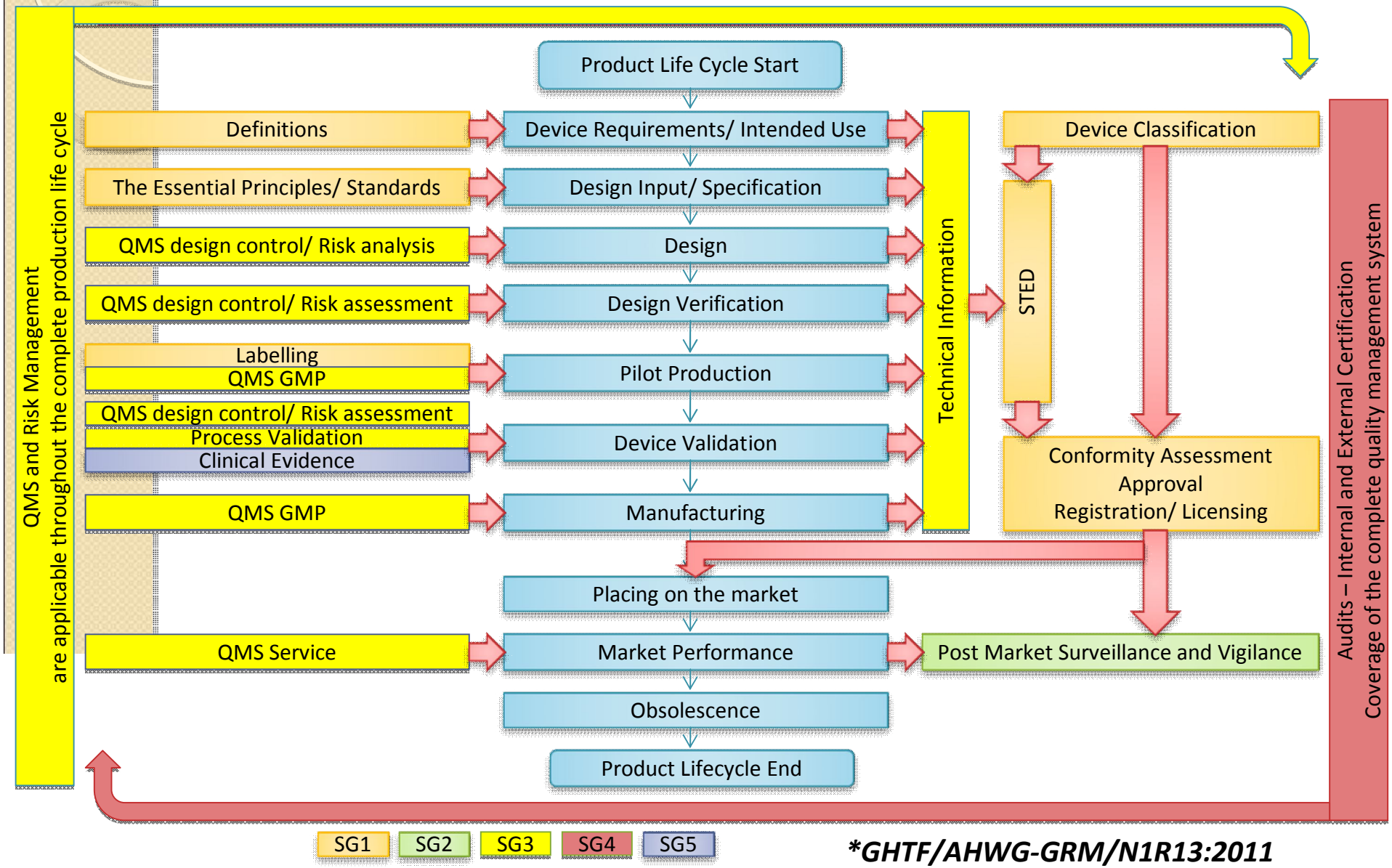
- History & Performance of GHTF
- Final Report from Study Groups
- Implementation of GHTF guidance & new regulatory initiatives
  - Australia, Canada, EU, USA, Japan & AHWP
- IMDRF – overview and update on work items
- Global Hot Topics
  - UDI
  - ISO 13485
  - New Technology
  - GMDN
  - Software
  - Single Audit

Legacy of GHTF – Final Documents

- Steering Committee: 4
- Study Group 1 (incl. IVD sub-group): 12
- Study Group 2 : 7
- Study Group 3 : 5 (and ISO13485 etc.)
- Study Group 4 : 6
- Study Group 5 : 8
- Ad Hoc Working Group: 2 (UDI, Regulatory Model)

The GHTF Regulatory Model

(overall view on GHTF guidance documents)



**GHTF/AHWG-GRM/N1R13:2011*

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GHTF Closing Statement

GLOBAL HARMONIZATION TASK FORCE

Working Toward Harmonization in Medical Device Regulation

GHTF CLOSING STATEMENT
November 2012

The Global Harmonization Task Force (GHTF) was established in 1992 for the purpose of encouraging harmonization in regulatory requirements and practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

As the chair of the GHTF, I would like to thank all who have been working for and involved in the GHTF.

GHTF Closing Statement (1)

The Global Harmonization Task Force (GHTF) was established in 1992 for the purpose of encouraging harmonization in regulatory requirements and practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade.

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GHTF Closing Statement (2)

The GHTF published dozens of important guidance documents including the GHTF Regulatory Model as the result of the hard work and significant contribution from regulators, industry, academia and other stakeholders. These documents have been implemented into the medical device regulations in many countries not only the five founding member nations but also other countries.

GHTF Closing Statement (3)

The International Medical Device Regulators Forum (IMDRF) was launched in February 2012. This new regulatory forum stands on the strong foundation of the GHTF. I believe it will play an important role in the future work of the IMDRF to achieve further convergence of medical device regulations around the world.

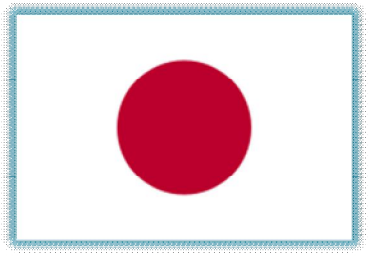
GHTF Closing Statement (4)

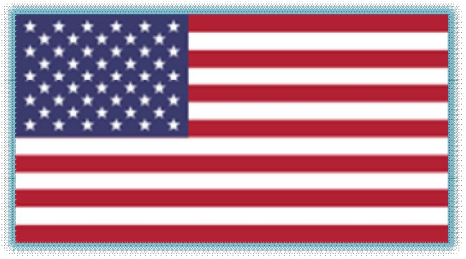
Once again, I would like to express my great appreciation to all of the members and organizations involved in the GHTF for their great contributions and to celebrate the launch of the IMDRF and its future achievements based on the 20 years history of the GHTF.

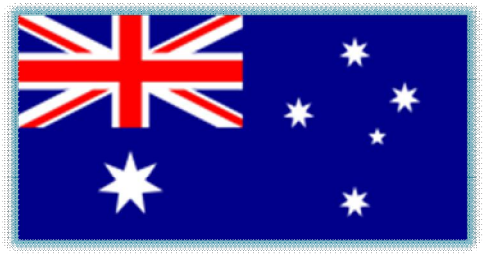
November 2012

GHTF Chair

Kazunari Asanuma







Thank you!