

*11th Conference of the Global
Harmonization Task Force*

STUDY GROUP 1

Status Report

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Study Group 1 Update

- I. Expansion of Study Group 1
 - AHWP
 - PACME and Latin American Industry
- II. Update on SG1 Work Plan
 - The Global Regulatory Model
 - Final documents
 - Documents in progress
 - Upcoming document revisions
- III. Barriers to Harmonization

Expansion of Study Group 1

- Study Group 1
 - Balanced participation by regulators & industry from all founding jurisdictions
 - Separate IVD Medical Devices Subgroup
 - Expansion of SG1 to include non-founding members
 - Regulatory Authorities
 - Industry Associations

Expansion of Study Group 1

- Recognition of the growing interest in SG 1 documents in non-member countries
 - AHWP
 - ASEAN
 - PACME
 - Latin American industry groups

Expansion of Study Group 1

Non-founding member nations -

– Regional harmonization efforts

- AHWP Common Submission Dossier Template
- ASEAN 2010 Commitment
- Translation of GHTF docs into Spanish and Portuguese

– Record of positive contributions to SG1

– Increasing share of global production/ market

Expansion of Study Group 1

- Joint meetings with SG1:
 - AHWP (Kyoto) - Feb. 2007
 - Latin American delegates (Washington, D.C.) - Oct. 2007
- 2007: Permanent inclusion of 2 delegates each from Asia & Latin America into SG1
- Balanced representation by regulators & industry

Expansion of Study Group 1

Expansion Goals of SG1:

- give greater voice to non-founding members
- account for diversity of perspectives
- respond to different needs among regions & nations

Update on SGI Work Plan

- The Global Regulatory Model
- Final documents
- Documents in progress
- Upcoming document revisions

The Global Regulatory Model

GHTF guidelines

- reflect joint experience of regulators/industry
- create a globally harmonized model
- provide a useful framework for medical device regulation
- initiate the establishment of similar regulatory requirements & elimination of nation-specific regulatory practices

The Global Regulatory Model

SG1 is concerned with -

- key principles of device regulation
- key definitions that underlie device regulatory systems
- certain elements of conformity assessment

The Global Regulatory Model

A number of SG1 guidelines figure prominently within the global regulatory model:

- provide a definition of “medical device”
- provide a definition of “manufacturer”
- describe device classification principles
- identify essential principles of safety & performance
- identify conformity assessment elements applicable to each class of devices

SG1 Final Documents

SG1/N29:2005 *Information Document Concerning the Definition of the Term “Medical Device”*

SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*

SG1/N15:2006 *Principles of Medical Devices Classification*

SG1/N040:2006 *Principles of Conformity Assessment for Medical Devices*

SG1/N43:2005 *Labelling for Medical Devices*

SG1/N012 *Role of Standards in the Assessment of Medical Devices (18 November 1999)*

SG1 Documents in Progress

Document	Status/Priority	Target for completion
SG1/N011 (PD) <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles (STED)</i>	Proposed for advancement as Final Document Priority 1	Final Document 2007 / Q4
SG1(PD)/N044 <i>Role of Standards in the Assessment of Medical Devices</i>	Proposed for advancement as Final Document Priority 1	Final Document 2007 / Q4

SG1 Documents in Progress

Document	Status/Priority	Target for completion
SG1(WD)/N055 <i>The definition of the Term Manufacturer and Related Entities.</i>	Working Draft, under development by SG1/SG3/SG4 Priority 2	Proposed Document 2008 / Q4
SG1(WD)/N065 <i>Registration of manufacturers and their medical devices by the Regulatory Authority</i>	Working Draft – joint SG1/SG3/SG4 effort Priority 2	Proposed Document 2008 / Q4

SG1 Document Revisions

Document	Status/Priority	Target for completion
SG1-N29:2005 <i>Information Document Concerning the Definition of the Term "Medical Device"</i>	Revision to begin in 2008 Priority 3	Proposed Document 2009 / Q2
SG1-N41:2005 <i>Essential Principles of Safety & Performance of Medical Devices</i>	Revision to begin in 2008 Priority 3	Proposed Document 2009 / Q2
SG1-N43:2005 <i>Labelling for Medical Devices</i>	Revision to begin in 2008 Priority 3	Proposed Document 2009 / Q2

Barriers to harmonization

Harmonization:

- stepwise process
- shaped by multiple domestic & international needs
- often requires legislative change & promulgation of new regulations

Barriers to harmonization

Which SG1 documents present the greatest challenge for harmonization?

SG1/N15:2006 Principles of Medical Devices
Classification

SG1/N040:2006 Principles of Conformity
Assessment for Medical Devices

Barriers to harmonization

Classification & Conformity Assessment:

- Deviations in assignment of class undermine harmonizing efforts
- Differences in class = differences in conformity assessment requirements
- Progress towards harmonization achieved so far among founding members
- What about other jurisdictions?

Barriers to harmonization

Primary focus of GHTF has been:

– development of guidelines

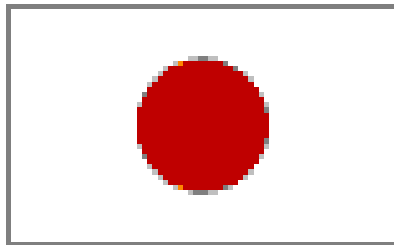
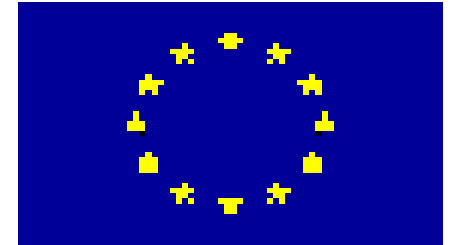
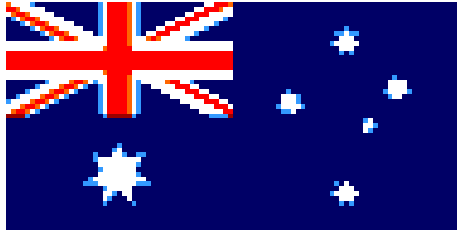
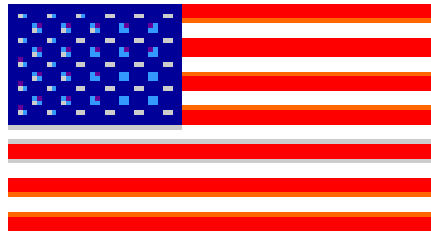
Focus of GHTF is shifting towards:

– exploring barriers to implementation

– implementation of guidelines

We must remind ourselves that implementation:

- *is the work of regulators & industry*
- *requires sustained & committed efforts*



Thank You ...