4th APEC-Funded Seminar on Harmonization of Medical Device Regulation

STUDY GROUP 1

Accomplishments & Future Direction

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Accomplishments & Future Work

- SG 1 Mission
- SG1 Membership, Structure and Participation
- Expansion of Study Group 1
- Update on SG1 Work Plan
- Summary Comments

Study Group 1 Mission

- Production of harmonized guidelines on medical device regulatory practices
- Focused on safety & performance of medical devices
- Scope – all products that fall within definition of GHTF/SG1/N029:2005 (including IVDMDs)

Structure, membership & participation

Structure

- "Parent" Study Group 1
- IVD Medical Devices Subgroup

SG1 Leadership:

- Ginette Michaud - Chairperson
- Benny Ons - Vice-Chairperson
- Alan Kent - Secretary
- Nancy Shadeed – IVD Medical Devices Subgroup Chairperson

Structure, membership & participation

- SG1 membership is characterized by diversity:
  - market size
  - age of medical device regulatory programs
  - relative percentage of domestic versus foreign manufacturers
  - role of Notified Bodies
  - relative roles of national versus supra-national or provincial entities

Structure, membership & participation

- Participation:
  - voluntary
  - funded by individual members
  - members recognize great potential of harmonization
  - members feel constant tug between harmonization & independent progress

Structure, membership & participation

- Membership:
  - Balanced representation by regulators and industry
  - Balanced representation from each of three regions:
    - Japan and Australia
    - European Union
    - North America
  - Expansion to include non-founding members

Expansion of Study Group 1

Recognition of regional harmonization efforts in non-founding member nations:

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

Non-founding members have:

- Record of positive contributions to SG1
- Increasing share of global production/ market

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

Expansion of Study Group 1

Expansion efforts of SG1

Joint meetings:

- SG1 & AHWP in Kyoto Feb. 2007
- SG1 & Latin American/Caribbean delegates in Washington, D.C. Oct. 2007

- In 2007: Invitation for permanent inclusion of 2 delegates each from Latin America/Caribbean and AHWP into SG1

Update on SG1 Work Plan

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

The Global Regulatory Model

SG1 guidelines are key elements of global regulatory model. They:

- define “medical device”
- define “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) *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles (STED)*	**Proposed for advancement as Final Document** **Priority 1**	**Final Document 2008 / Q1**
SG1(PD)/N044 *Role of Standards in the Assessment of Medical Devices*	**Proposed for advancement as Final Document** **Priority 1**	**Final Document 2008 / Q1**

SG1 Documents in Progress

Document	Status/Priority	Target for completion
SG1(WD)/N055 *The definition of the Term Manufacturer and Related Entities.*	**Working Draft, under development by SG1/SG3/SG4** **Priority 2**	**Proposed Document 2008 / Q2**
SG1(WD)/N065 *Registration of manufacturers and their medical devices by the Regulatory Authority*	**Working Draft – joint SG1/SG3/SG4 effort** **Priority 2**	**Proposed Document 2008 / Q4**

SG1- IVDMD Documents in Progress

Document	Status/Priority	Target for completion
SG1/N045 *Principles of Classification of In Vitro Diagnostic Medical Devices*	**Proposed for advancement as Final Document Priority 1**	**Final Document 2008 / Q2**
SG1/N046 *Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices*	**Proposed for advancement as Final Document Priority 1**	**Final Document 2008 / Q2**
STED for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.	**First working draft in preparation** Priority 2	**Proposed Document 2008/Q4**

SG1 Upcoming Document Revisions

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

Summary Comments

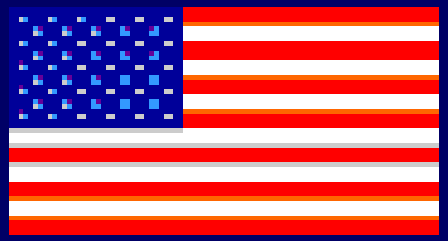
- Harmonization is *challenging work*
  - need to develop a common vision
  - obstacles posed by existing statutes & regulations
  - step-wise progress is unavoidable

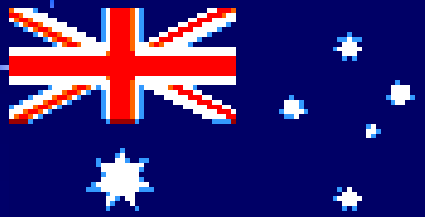
Summary Comments

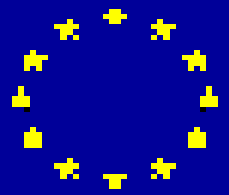
- Successful harmonization requires:
  - inclusiveness so that diverse viewpoints are considered
  - meaningful partnership between regulators & industry
  - commitment to long term goals

Summary Comments

Thank you for your attention.







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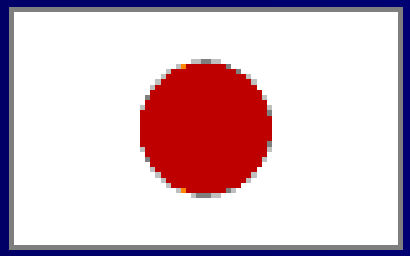

Thank You …