Global Harmonization Task Force
Study Group 1

Accomplishments & Future Direction

Ginette Y. Michaud, MD
Chairperson, Study Group 1

Meeting of GHTF Study Group 1

with the

Asian Harmonization Working Party

Kyoto, Japan
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Agenda

I. SG 1 Mission
II. SG1 Membership, Structure and Participation
III. Work Products
IV. Current and Future Work
V. Summary Comments

Study Group 1 Mission

- Premarket regulation -
  - Production of harmonized guidelines on premarket regulatory oversight
  - Focused on safety & performance of medical devices
  - Scope – all products that fall within definition of GHTF/SG1/N029:2005 (including IVDDs)

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

- Membership:
  - Balance representation by regulators and industry
  - Balanced representation from each of three regions:
    - Japan and Australia
    - European Union
    - North America
  - New participation by delegates from AHWP

Structure, membership & participation

- SG1 Membership (continued):
  - Significant diversity:
    - market size
    - duration 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
  - recognition of great potential of harmonization
  - constant tug between harmonization and independent progress

Work Products

- What is a Medical Device?
  ⇨⇨⇨⇨⇨ **SG1/N029:2005**
- What are the Essential Principles of Safety & Performance?
  ⇨⇨⇨⇨⇨ **SG1/N041:2005 (Essential Principles)**
- How will the manufacturer meet the Essential Principles?
  ⇨⇨⇨⇨⇨ **SG1/N012:1999** (Standards)
  ⇨⇨⇨⇨⇨ **SG1/N043:2005** (Labelling)

Work Products

- What is the Class of the Device?
  - ⇨⇨⇨⇨⇨ **SG1/N015:2006** (Classification)
  - ⇨⇨⇨⇨⇨ (IVD Classification)
- What Conformity Assessment procedures should be applied?
  - ⇨⇨⇨⇨⇨ **SG1/N040:2006** (Conformity Assessment)
  - ⇨⇨⇨⇨⇨ (IVD Conformity Assessment)

Current and Future Work - STED

STED:

- SG1/N011R17 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- Proposed document in 2003 – under revision based on accumulated experience
- STED for IVD Medical Devices – new work item proposal adopted in November 2006

Current and Future Work - Role of Standards

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

- Revised in 2006 to include transition period and to recommend
  - the recognition of updated standards
  - the use of superseded standards
- Proposed document – comment period ending March 15, 2007

Current and Future Work - Definition of "manufacturer"

Definition of "manufacturer":

- Definition of the term "manufacturer" & terms for related entities involved in
  - manufacturing a device
  - placing the device on the market, and/or
  - selling the device
- the use of these terms not harmonized between jurisdictions
- harmonized definition to increase consistency & transparency of regulatory controls
- work to be undertaken in collaboration with SG2, SG3 and SG4.

Current and Future Work - Registration of "manufacturer"

Registration of manufacturers & their medical devices:

- one of five conformity assessment elements in *GHTF/SG1/N40:2006 Principles of Conformity Assessment*
- essential component of a regulatory framework
- Lack of harmonization between jurisdictions
- Goal to harmonize terms, definitions, scope and content of registration
- Guideline to clarify responsibilities of regulator & manufacturer

Summary comments

- Harmonization is *hard work*
  - development of common vision
  - obstacles posed by existing statutes and regulations
  - step-wise progress is unavoidable

Summary comments

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

Summary Comments

Thank you for your attention.