Global Harmonization Task Force

STUDY GROUP 1

Globally Harmonized Premarket Oversight

presented at

GHTF Joint Study Group Meeting

Hilton Washington DC September 16, 2005

Ginette Y. Michaud, MD
Global Harmonization Task Force
Study Group 1

- Introduction to GHTF Study Group 1
  - purpose
  - scope
  - structure
  - membership

- Guidelines
  - final documents
  - work in progress

- Lessons learned
Introduction to SG1 - purpose

- Development of harmonized guidelines on the operational aspects of premarket regulatory oversight
  - Comparison of regulatory systems
  - Harmonization of common practices
  - Identification of obstacles to uniform regulations

- Focused on safety & performance of medical devices
Introduction to SG1 - scope

- Scope - all devices that fall within definition:

  GHTF/SG1/N029:2005 Information Document Concerning the Definition of the Term “Medical Device”

  * this includes In Vitro Diagnostic Devices
Introduction to SG1 - Structure

- "Parent" Study Group
- IVDD Subgroup
  - Chairperson – Ginette Michaud (FDA)
  - Secretary – Alan Kent (UK)
  - Subgroup Chair – Nancy Shadeed (Health Canada)
Introduction to SG1 - membership

- largest membership of all Study Groups
  - SG1 n = 27
  - SG2 n = 15
  - SG3 n = 11
  - SG4 n = 17
  - SG5 n = 17
Introduction to SG1 - membership

- All founding member nations
- Regulatory authorities and Industry associations
- Strong interest by other parties
Study Group 1

Guidelines

- Focus on premarket aspect of medical device regulatory systems
- Goal: produce harmonized guidelines
- Tension between national regulations & harmonized guidelines
- May or may not include IVDDs
Study Group 1

final guidelines

- GHTF/SG1/N029:2005 *Information Document Concerning the Definition of the Term “Medical Device”*
  - key document
  - includes IVDDs
  - cross-cutting

- goal: reduce global diversity of regulatory schemes and facilitate harmonization
Definition of a medical device:
“...any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software...”
“...intended...for human beings for...diagnosis, prevention, monitoring, treatment of disease...”
“...intended...for... providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body...”
“...does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means...”
<table>
<thead>
<tr>
<th><strong>Study Group 1</strong></th>
<th><strong>final guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GHTF/SG1/N43: 2005 Labelling for Medical Devices</strong> <em>(including IVDDs)</em></td>
<td></td>
</tr>
<tr>
<td>- device identity and intended purpose</td>
<td></td>
</tr>
<tr>
<td>- how to use, maintain &amp; store device</td>
<td></td>
</tr>
<tr>
<td>- residual risks, warnings, contra-indications</td>
<td></td>
</tr>
<tr>
<td>- goal: reduce/eliminate differences between jurisdictions</td>
<td></td>
</tr>
</tbody>
</table>
Study Group 1
final guidelines

- GHTF/SG1/N041:2005 Essential Principles of Safety and Performance of Medical Devices (including IVDDs)
- describes requirements:
  - general requirements
  - specific design & manufacturing requirements of safety & performance
- goal: allows demonstration of suitability of device for intended purpose
Study Group 1

**final guidelines**

- GHTF/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices (undergoing revision)
  - supports development of consensus standards
  - supports “recognition” by RA of standards for demonstrating conformity to Essential Principles
  - encourages compliance with standards by medical device industry
  - use of standards is voluntary

- goal: ensure safety, quality, performance of medical devices
Study Group 1
draft guidelines

- **SG1/N015 Principles of Medical Devices Classification**
  - system of rules that assigns devices to one of four risk classes (A, B, C, D)
  - classification subsequently allows the application of regulatory controls that increase with increasing degree of risk

- Goal: to assist allocation by manufacturer of medical device to appropriate risk class
Study Group 1

draft guidelines

- SG1/N040 Principles of Conformity Assessment for Medical Devices
  - identifies conformity assessment elements:
    - quality management systems
    - summary technical documentation
    - declaration of conformity
    - system for postmarket surveillance
    - registration of manufacturers and medical devices
Study Group 1

draft guidelines

- **SG1/N040 (continued)**
  - concept of increased scrutiny, evidence requirements & conformity assessment procedures for higher risk devices
  - description of manufacturer’s responsibility for each element, e.g., establishment of QMS, submission of STED, etc.,
  - description of RA’s responsibility for each element, e.g., premarket audit of QMS, review of submitted STED, etc.

- Goal: global convergence of medical device regulatory systems
GHTF/SG1/N11:2002 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)
- Describes content and format of subset of technical documentation to be held or submitted for conformity assessment procedures

Goal: harmonize the documentation of evidence of conformity to essential principles
Study Group 1
draft guidelines

- **SG1/N045 Principles of In Vitro Diagnostic Devices Classification**
  - system of rules that assigns devices to one of four risk classes (A, B, C, D)

- **SG1/N046 Premarket Conformity Assessment for In Vitro Diagnostic Devices**
Study Group 1

Lessons Learned

- The “secret lives” of draft guidelines
  - Adopted in draft into new regulations
  - “Premature death” because of delay to completion or failure to adopt by founding members
- “Hidden output”
  - “Learning by doing”
  - New avenues of communication between organizations

Thank you for your attention.