

11th Conference of the Global Harmonization Task Force

Needs, Barriers and Constraints Associated with
National Implementation

The Present Situation

Ginette Y. Michaud, MD
Chairperson, Study Group 1

Workshop 1: Regulatory Model for Development of Device
Regulatory Systems

October 4, 2007

The Present Situation

The findings and conclusions expressed are those of the presenter and do not represent any determination or policy by the US Food and Drug Administration

The Present Situation

The Survey Tool

- GHTF Guidance Implementation Survey

Analysis of Results

- Adoption of GHTF guidelines
- Adoption by statute/regulation versus guidance

What have we learned?

Concluding Remarks

The Survey Tool

- Guidance Implementation Survey date: 2007
- Query – harmonization & implementation status
- Purpose: report on adoption of harmonized guidelines
- Survey respondents – GHTF founding regulators

The Survey Tool

- Self-reporting
- Descriptive responses
- No requirement for in-depth legal analysis
- No prior definition for “harmonized” or “adopted”

The Survey Tool

- Scoring system developed post-survey as a means of comparison between jurisdictions
- Descriptive responses
- Implementation status scored according to level of adoption:
 - Adopted in full
 - Adopted in part
 - Adoption pending
 - Not adopted

The Survey Tool

- “Adopted” refers to –
 - interpretation of existing law, regulation or guidance
 - statutory and/or regulatory changes, or
 - new guidance, policy or procedure
- “Not adopted” refers to –
 - non adoption due to legal impediment,
 - no determination at time of survey, or
 - no response or “not applicable”

Analysis of Results

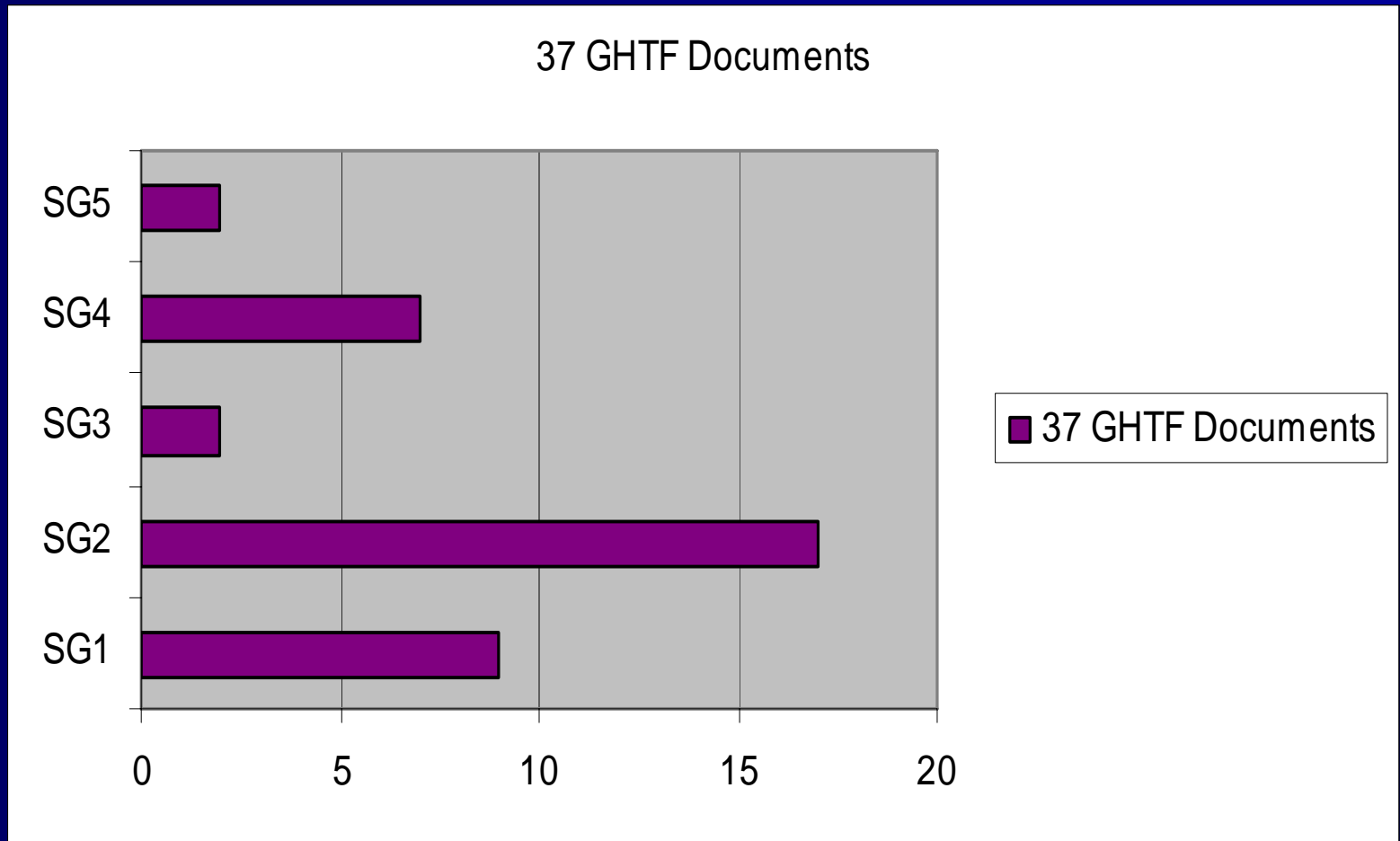
Comparison between jurisdictions:

- Adoption of GHTF guidelines
- Adoption by statute/regulation versus guidance

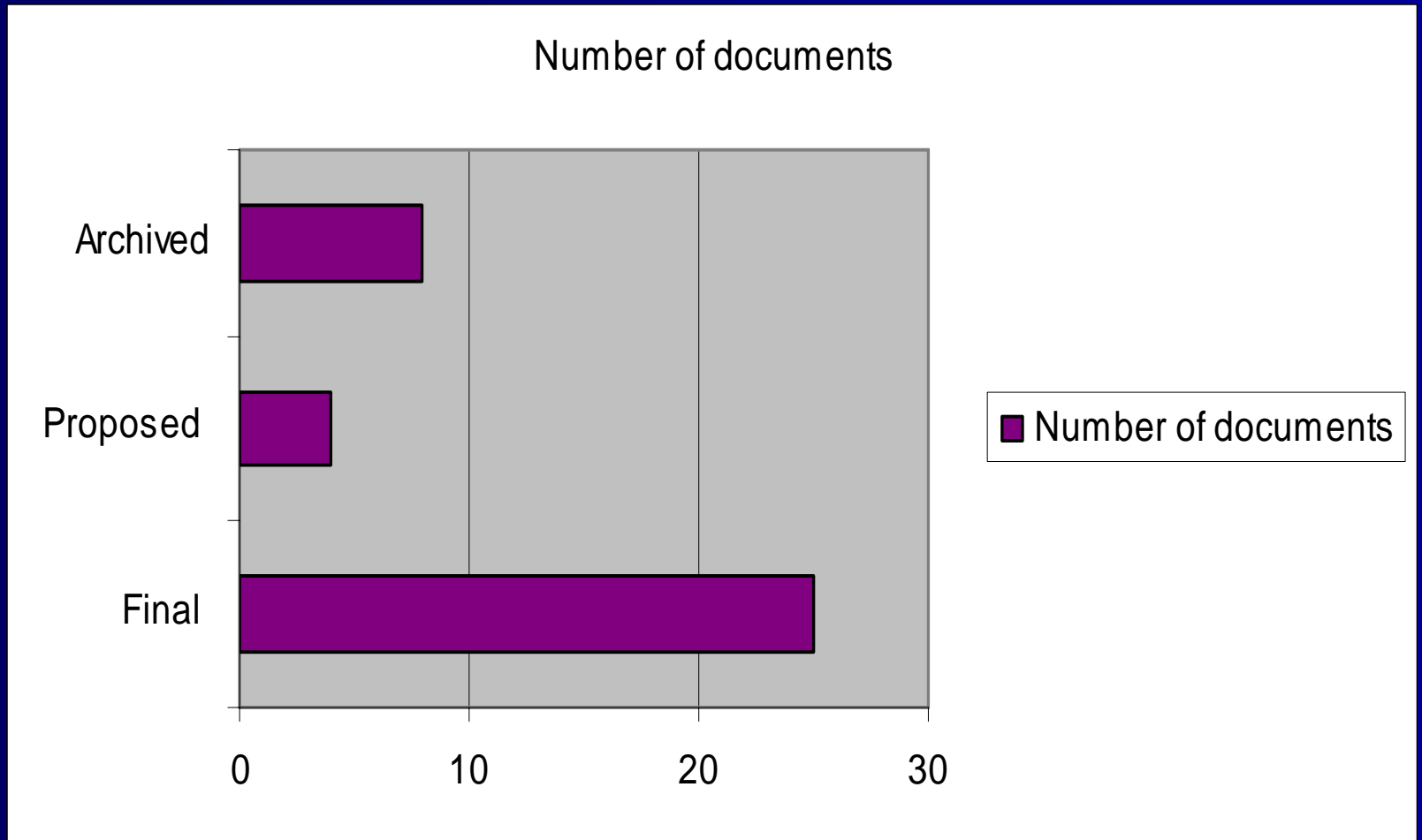
Important factor:

- Responses influenced by interpretation of survey questions

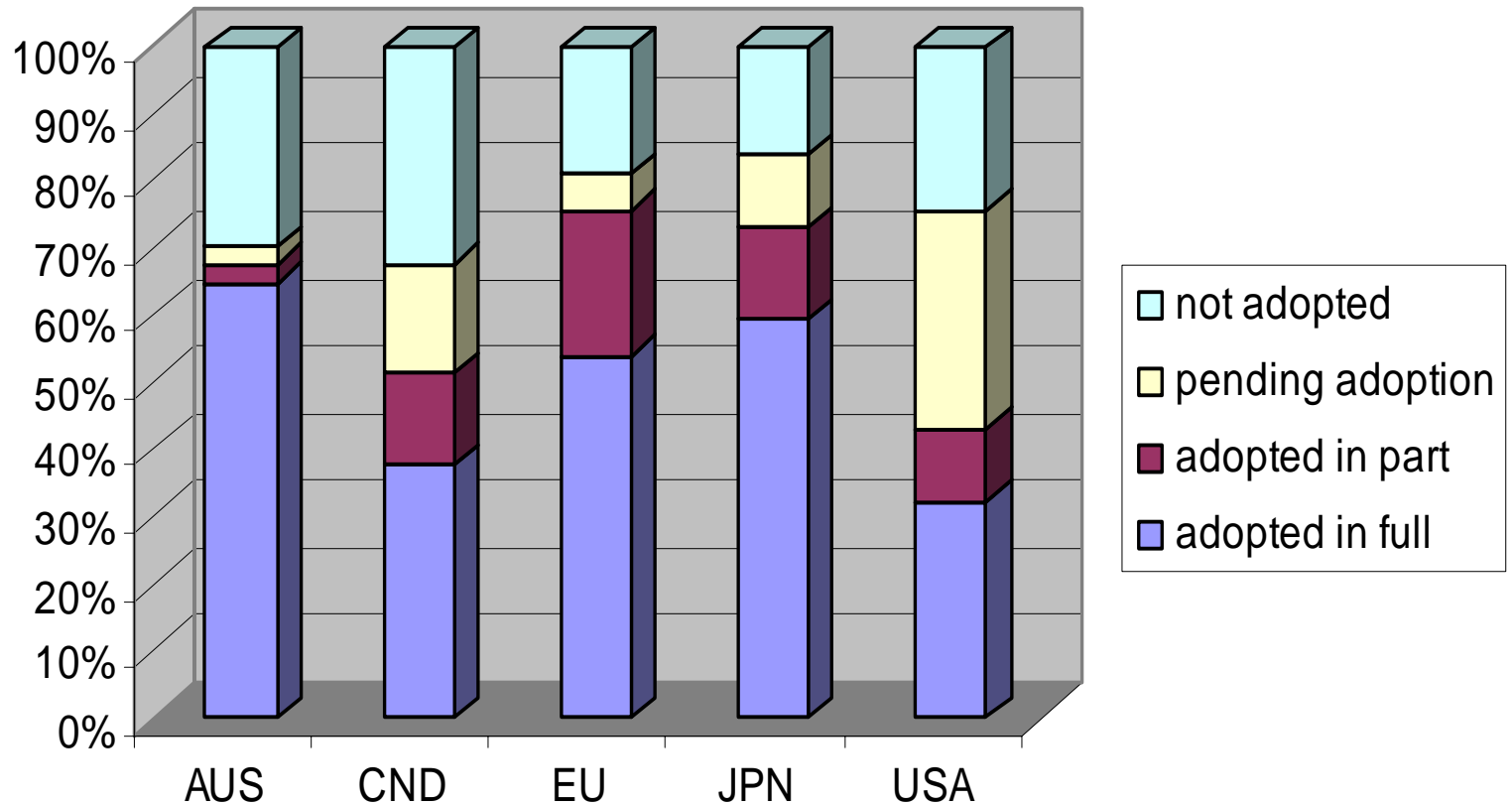
Distribution of Documents



Document stage of development



Adoption of GHTF guidelines – comparison between jurisdictions



Adoption of GHTF guidelines – comparison between jurisdictions

- Information trends more meaningful than specific results
- Apparent differences in progress across jurisdictions
- Greater level of “adopted in full” in jurisdictions with recent legislative efforts
- Considerable % of “not adopted” among members

Adoption of GHTF guidelines – comparison between jurisdictions

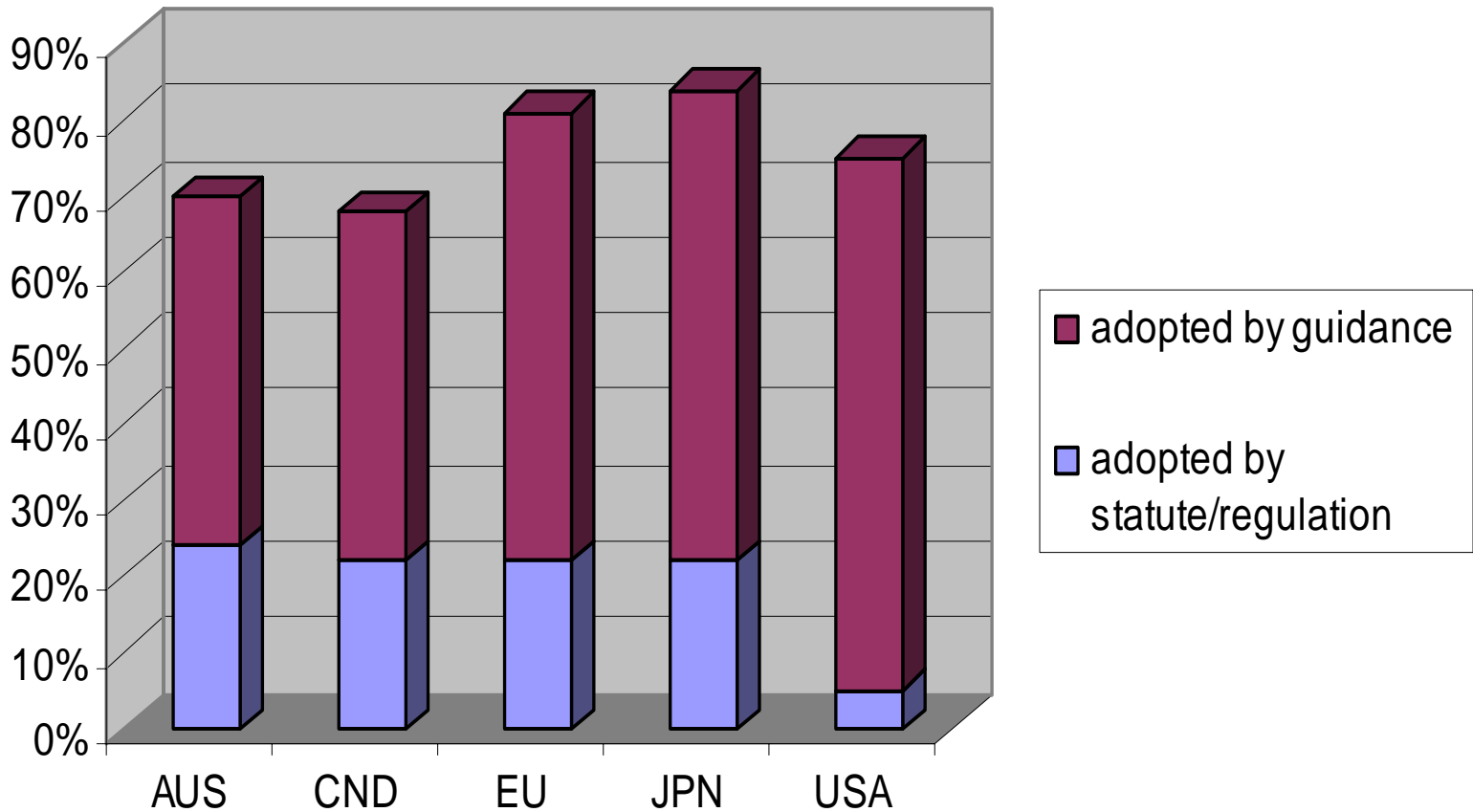
- Highest percentage of
 - “adopted in full” – AUS, JPN & EU
 - “adopted in part” – EU, CND, JPN
 - “pending adoption” – USA
 - adoption overall – JPN, EU
- No evidence of preferential adoption of documents from certain Study Groups

Adoption of GHTF guidelines – comparison between jurisdictions

Not adopted:

- legal impediment, n = 1
- “not applicable”
- “under consideration”
- archived - “obsolete”
- “potential for adoption – undetermined”

Adoption by statute/regulation versus guidance



Adoption by statute/regulation versus guidance

- Greater adoption of GHTF guidelines through guidance
- Possible explanations:
 - GHTF guidelines are written as guidance
 - Development of guidance under the control of Regulatory Authorities
 - New guidance more easily accepted - less prescriptive/non binding

Adoption by statute/regulation versus guidance

- Lesser harmonization through new statutes or regulations
- Possible explanations:
 - Legal framework not easily changed
 - Change may be more difficult in countries with mature systems
 - Countries vary in terms of political & legislative systems

What have we learned?

Implementation survey:

- Survey is not definitive - assessment of implementation status remains preliminary
- provides insight into existing harmonization trends
- informs the design of more definitive surveys
- serves as a starting point for more detailed assessments, e.g. GHTF Retrospective analysis

What have we learned?

Since 1992:

- adoption of a majority of GHTF guidelines, in part or in full
- the regulation of medical devices is undergoing harmonization among founding members

However, manufacturers are still faced with multiple requirements, multiple audits, multiple submissions...across jurisdictions.

What have we learned?

Can these results be considered a success?

Survey indicates that:

- Regulatory convergence is not complete.
- Many differences remain between national regulatory practices and GHTF guidelines.

What have we learned?

Harmonization is a step-wise process:

- Survey results reflect the first step in establishing similar regulatory requirements across jurisdictions.
- The second step will be a translation of guidance into multiparty actions (e.g., single QS audit to satisfy multiple regulators).

Evidence of incremental progress is encouraging.

Closing thoughts

- Survey – preliminary assessment of progress achieved to date.
- Much work remains.
- Harmonization is the responsibility of both regulators and industry.
- Sustained effort will be required of both parties for many years to come.

Closing thoughts

Thank you to Mr. Tim Ulatowski of the US FDA for his compilation and analysis of study findings.