Global Harmonization Task Force

STUDY GROUP 1

Globally Harmonized Premarket Oversight

presented at

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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

- 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

Study Group 1 final guidelines

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…"

Study Group 1 final guidelines

- GHTF/SG1/N43:2005 Labelling for Medical Devices *(including IVDDs)*
  - device identity and intended purpose
  - how to use, maintain & store device
  - residual risks, warnings, contra-indications
  - goal: reduce/eliminate differences between jurisdictions

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

Study Group 1 draft guidelines

- 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.