14th Asian Harmonization Working Party Meeting

STUDY GROUP 1

Building a Model for the Harmonized Regulation of Medical Devices

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GHTF Study Group Updates
Hong Kong SAR
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Building a Model for the Harmonized Regulation of Medical Devices

- Study Group 1 Guidelines within the Global Regulatory Model
- Collaboration with the AHWP
- Concluding remarks

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

Study Group 1 Guidelines within the Global Regulatory Model

Study Group 1: Premarket Evaluation

- Supports convergence of medical device regulatory systems through the development of harmonized guidelines.
- Guidelines address various elements of a global regulatory model.

Study Group 1 Guidelines within the Global Regulatory Model

SG1 Guidelines contain –

- harmonized recommendations for best practices
- recommendations for medical devices and IVD medical devices

SG1 Guidelines reflect –

- collective experience
- aspirations for globally harmonized practices
- substantial agreement among partners

Study Group 1 Guidelines within the Global Regulatory Model

SG1 Guidelines serve as a guide –

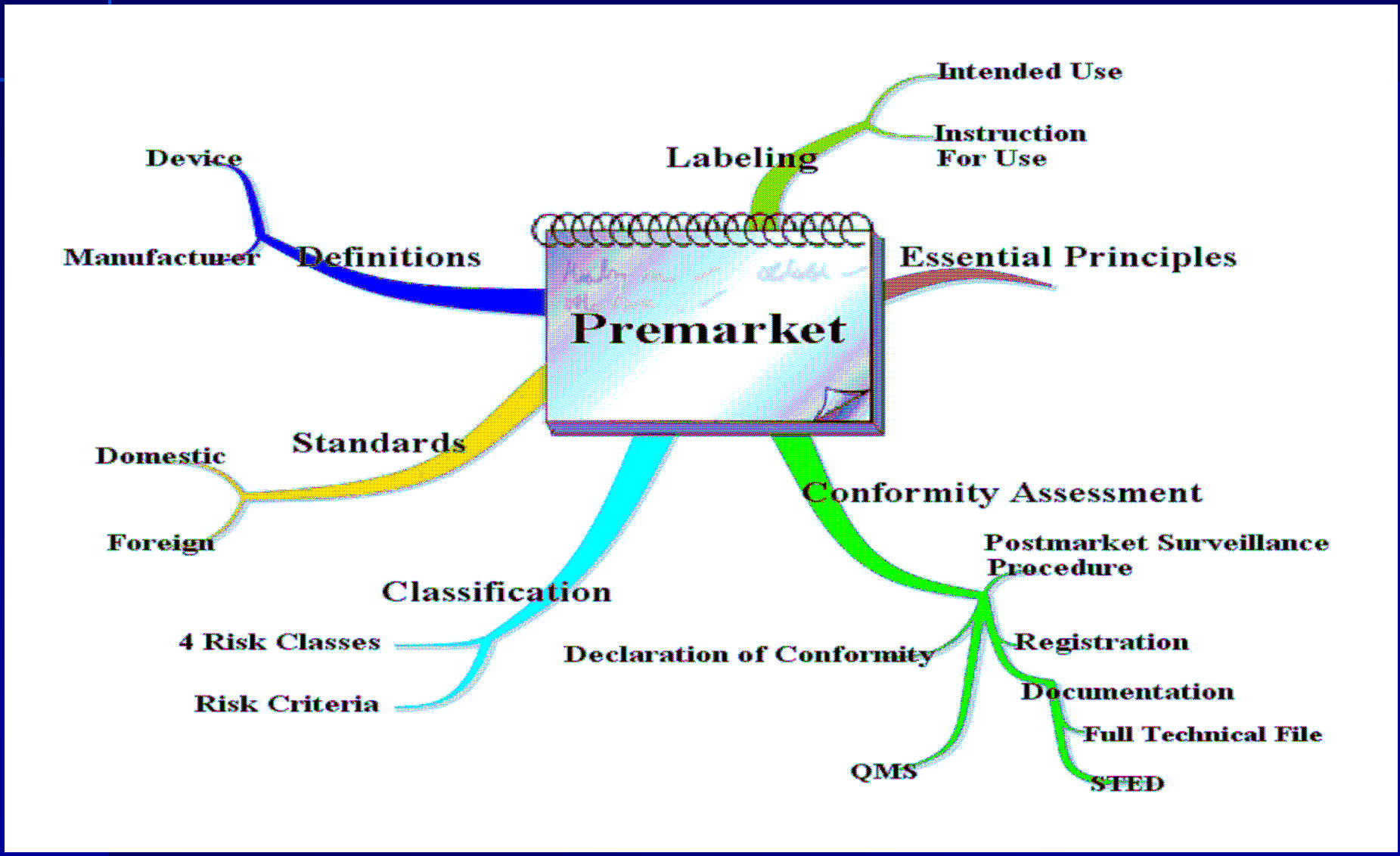
- for experienced regulators seeking harmonization
- for new regulators wishing to establish a globally harmonized system

SG1 Guidelines serve as a tool –

- for more effective inter-jurisdictional communication
- for training of new regulators

Global model – Premarket Phase

**GHTF/AHWG(PD1)/N1R5 Global Harmonization Task Force Medical Device Regulation Model*



Study Group 1 Guidelines within the Global Regulatory Model

Primary Guidelines:

- Key Definitions
- Essential principles of Safety & Performance
- Principles of conformity assessment
- Principles of Classification

Secondary Guidelines:

- Registration & Listing
- Summary Technical Documentation
- Role of standards
- Labelling

Key Definitions

- Key definitions are the starting point for any regulatory system:
  - SG1(PD)/N055 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer
  - SG1/N029:2005 Information Document Concerning the Definition of the Term "Medical Device"

MANUFACTURER
AUTHORIZED REP
DISTRIBUTOR
IMPORTER

MEDICAL DEVICE
&
IVD
MEDICAL DEVICE

Essential Principles

Essential Principles of Safety and Performance:

Safe & Effective Medical Devices

- for ensuring the safety & performance of medical devices
- address fundamental design, manufacturing & labelling requirements
  - SG1/N041:2005 Essential Principles of Safety & Performance of Medical Devices

Assessment of Conformity

Principles of Conformity Assessment -

- provide a framework for harmonized regulation of medical devices
- describe fundamental requirements for regulators & industry
- rooted in Essential Principles of Safety & Performance
- key to understanding relationship of SG1 guidelines within the global model

Principles of Conformity Assessment

CONFORMITY ASSESSMENT OF QMS

QUALITY MANAGEMENT SYSTEM

SYSTEM FOR POST-MARKET SURVEILLANCE

REGISTRATION/LISTING

REGISTRATION OF MANUFACTURERS

LISTING OF MEDICAL DEVICES

CONFORMITY ASSESSMENT OF DEVICE SAFETY & PERFORMANCE

SUMMARY TECHNICAL DOCUMENTATION (STED)

DECLARATION OF CONFORMITY

Assessment of Conformity

- *Assessment of conformity to Essential Principles:*
  - *SG1/N040:2006 Principles of Conformity Assessment for Medical Devices*
  - *SG1/N046:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*

Classification Principles

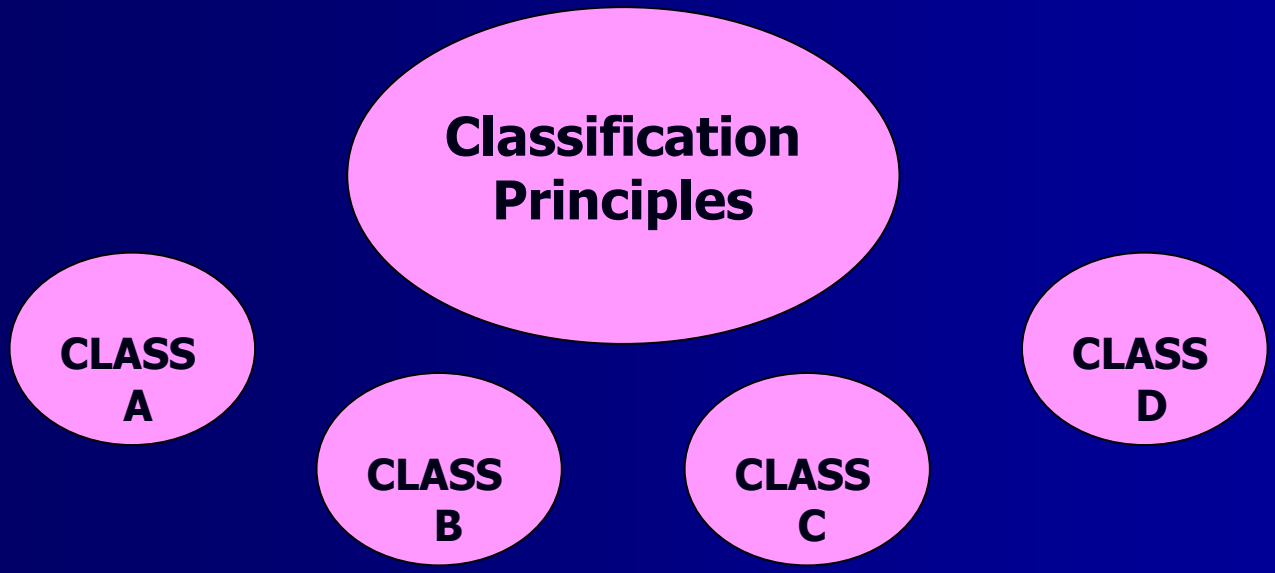
Principles of Classification –

- Four risk classes (Classes A to D)
- Rules-based classification scheme
- Class designation determines which conformity assessment requirements apply

Classification Principles

Principles of Classification –

- Lowest risk ----------> Highest risk



Classification Principles

Principles of Classification –

- SG1N015:2006
  Principles of Medical Devices Classification

- SG1/N045:2008
  Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Elements of Conformity Assessment

Elements of Conformity Assessment –

- SG1(PD)/N065
  Registration of Manufacturers and other Parties and Listing of Medical Devices
- SG1/N011:2008
  Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- SG1(PD)/N063 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices

Elements of Conformity Assessment

Elements of Conformity Assessment –

SG2, SG3 , SG4 and SG5 Documents –

- Study Group 2 – Post-Market Surveillance & Vigilance
- Study Group 3 – Quality Systems
- Study Group 4 – Auditing
- Study Group 5 – Clinical Evidence

Principles of Conformity Assessment

CONFORMITY ASSESSMENT OF QMS

QUALITY MANAGEMENT SYSTEM (SG3, SG4)

SYSTEM FOR POST-MARKET SURVEILLANCE (SG2)

REGISTRATION/LISTING

REGISTRATION OF MANUFACTURERS (SG1)

LISTING OF MEDICAL DEVICES (SG1)

CONFORMITY ASSESSMENT OF DEVICE SAFETY & PERFORMANCE

SUMMARY TECHNICAL DOCUMENTATION (STED) (SG1) (SG5)

DECLARATION OF CONFORMITY (SG1)

Study Group 1 Guidelines within the Global Regulatory Model

Other Secondary Guidelines -

Tools for conforming to the Essential Principles -

- SG1/N043:2005
  Labelling for Medical Devices
- SG1-N012R10
  Role of Standards in the Assessment of Medical Devices

Collaboration with AHWP

Study Group 1 Membership

Chairwoman – Ginette Michaud
Vice-Chairman – Benny Ons
Secretary – Alan Kent

Australia/Japan
Atsuchi Tamura, PDMA
(Kentaro Azuma, MHLW)
Naoki Morooka, JFMDA
(Tomomichi Nakazaki, JFMDA)
Gary Burgess, TGA
Cliff Spong, MTAA

Asian Harmonization Working Party
Marianne Yap, Regulator, Singapore
Daphne Yeh, Industry, Chinese Taipei
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Mark Melkerson/FDA
Michael Morton/AdvaMed
Nancy Shadeed, Health Canada
Brenda Murphey/MEDEC

European Union
Peter Bischoff-Everding, EC
Lennart Philipson, EU Regulator
Peter Linders/COCIR, EMIG
Carl Wallroth/EUROM VI, EMIG

IVD Medical Devices Subgroup Membership

Chairwoman – Nancy Shadeed
Secretary – Benny Ons

Australia/Japan
Shelley Tang, TGA
Jillianne Coles, IVD Australia
Sandra Russell, IVD Australia
Masaki Sugiura, PMDA
Kazutoshi Yamagishi, JAIMA
Yoko Ikeda, JACRI

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Jeffrey Chern, AHWP, Chinese Taipei
Essam Mohammed Y Al-Mohandis
AHWP, Saudi Arabia

North America
Maria Carballo, Health Canada
Matthew Gee, MEDEC
Francis Kalush, FDA
Andrea J. Casper, AdvaMed
Regina J. O'Meara, US Industry

European Union
Marie-Lise Migueres, Member State
Celine Bourguignon, EC
Michael Thein, EDMA
Petra Kaars-Wiele, EDMA

Collaboration with AHWP

February 2007, Kyoto, Japan:

- Joint meeting of AHWP and GHTF Study Group 1
- Start of AHWP representation in Study Group 1
- STED and CSDT discussions

Collaboration with AHWP

Ongoing discussions:

- Informal face to face meetings
- Teleconferences

Seeking increased interactions/collaboration between:

- GHTF Study Group 1

  and

- AHWP TC & AHWP WG01

Collaboration with AHWP

Opportunities for collaboration:

- STED and CSDT:
  - strong parallels
  - very similar content
  - further alignment should be sought
  - ultimate goal = one shared GHTF/AHWP harmonized document

Collaboration with AHWP

Opportunities for collaboration:

- GHTF Labelling guideline:
  - 'country of origin' issue
  - new text added to GHTF "Labelling" guideline explaining apparent contradiction between 'country of origin' requirement & requirements for medical device labelling
  - AHWP raised GHTF SG1's awareness of this issue

Collaboration with AHWP

Opportunities for collaboration:

- GHTF Classification and Conformity Assessment guidelines:
  - AHWP review of existing guidelines
  - Seeking AHWP recommendations to GHTF SG1 for revisions & resolution of comments
  - Goal: greater participation & input by AHWP on development of GHTF SG1 guidelines

Concluding Remarks

GHTF and AHWP serve harmonization in many ways:

- creating links between organizations
- identifying opportunities for harmonization
- leading and facilitating harmonization efforts
- setting the stage for implementation.

Thank you for your attention.