AHWP TC

PROPOSED STRATEGIC PLANNING FOR DISCUSSION
Asian Harmonization Working Party (AHWP)

- Asian Harmonization Working Party (AHWP)
  Established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.
- Vision
  To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry in Asia and other continents.
- Mission
  To Strategically Accelerate Medical Device Regulatory Convergence through Promotion of an Efficient and Effective Regulatory Model for Medical Devices.
GOALS

GOAL1
- To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

GOAL2
- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

GOAL3
- To promote capacity building in member economies and to foster strategic membership expansion.

GOAL4
- To work in collaboration with related international organizations such as International Medical Device Regulators Forum(IMDRF), WHO, ISO, IEC.
VISION

MISSION

GOAL 1
Develop framework for medical device regulations based on GHTF or WHO

Identify harmonization elements

Identify element of regulatory control

GOAL 2
Identify Policy to regulate premarket, placement & post market

Identify Priority Working Area (PWA) & experts

Consultation program

Annual workshop

Regulatory Updates

Attachment Programs

Regulatory Visit

Regulatory Documents Act, Regulation, Order, guidance documents, guideline, SOP, Standard Implementation by phases: Voluntary, transition, Mandatory

GOAL 3
Identify Policy to regulate premarket, placement & post market

Identify Priority Working Area (PWA) & experts

Consultation program

Annual workshop

Regulatory Updates

Attachment Programs

Regulatory Visit

Identify Competency Gaps and needs among members

Competency Program

Attachment programs

Identify Trainers

Training Programs

Regulatory Visit

GOAL 4
Identify Competency Gaps and needs among members

Competency Program

Attachment programs

Identify Trainers

Training Programs

Regulatory Visit

IMDRF

WHO

ISO

PAHO

APEC-LSIF
GOAL 1: To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

I. DEVELOP FRAMEWORK FOR MEDICAL DEVICE REGULATIONS BASED ON GHTF, IMDRF or WHO

- Premarket
  - QMS manufacturing activities
  - Testing
  - Clinical evaluation/clinical trial
- Placement
  - Establishment Licence
  - QMS for import/distribution
  - Product registration
  - Advertisement
- Post market
  - Recall
  - Distribution record
  - FSCA
  - Adverse event reporting
  - Auditing/Inspection

II. IDENTIFY HARMONIZATION ELEMENTS

- Medical device definition,
- classification,
- ESSENTIAL PRINCIPLES OF SAFETY & PERFORMANCE (EPSP)
- risk classification,
- COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)/csdt,
- standards for premarket, placement & postmarket

III. IDENTIFY REGULATORY ACTIVITIES under premarket, placement and post market, requirements, GD and relevant standards

- Premarket
  - manufacturing activities QMS ISO 13485
  - preclinical testing ISO 10993
  - Clinical trial ISO 14155
  - Testing
- Placement
  - Registration of medical device
  - Conformity assessment procedures ISO 17021
  - Assessments of MD based on EPSP
  - CSDT
  - Classification of MD
  - A bridge method of product verification
  - Special access
  - Establishment licence
  - QMS
  - GDP MD
  - Advertisement
- Post market
  - Distribution record
  - FCA
  - Recall
  - Mandatory problem reporting
  - Complaint handling
  - Maintenance
  - Disposal

IV. IDENTIFY POLICY TO REGULATE PREMARKET, PLACEMENT & POST MARKET (BY MEMBER ECONOMIES)

V. REGULATORY DOCUMENTS

- Act, Regulation, Order,
- GUIDANCE DOCUMENTS BY WG AHWP
- Guideline, SOP, Standard
- Regulatory Impact Study
- Good regulatory Practice (GRP)
- Implementation by phases: Voluntary, transition, Mandatory

VI. Programs on convergence and harmonization of medical device regulations in Asia and other continents.

a) Surveys on regulatory requirements based on framework
   - identify regulatory requirements in member economies
   - Current status
   - Identify gaps

b) Harmonization WP

To identify among member economies adoption of

- Definition MD
- Risk Classification ABCD, AMDC template
- CSDT-ACSDT template
- EPSP/standard

c) Adoption of AHWP/IMDRF GD

d) Impact study

e) GRP

f) Propose models: Voluntary, transition, Mandatory
GOAL 2
To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.

- Identify Priority Working Area (PWA) & experts (champion economy-member economy)
  - QMS
  - Product registration
  - Testing
  - Post market
- Attachment programs for regulators
- Country representative updates the secretariat
- Annual workshop to identify workprogram
- Regulatory updates during meeting
- Consultation Program: to provide assistance to develop regulatory document / system based on IMDRF/AHWP(WG)
- Regulator Visitation Program
GOAL 3
To promote capacity building in member economies and to foster strategic membership expansion.

- Survey among member economies (country representatives to update)
- Identify Gaps and needs among member state
- Develop competency program
- Develop curriculum for regulator/industry
- Identify Trainers (CORE) among member economies-AHWP
- List of training module
- Training program - In house/Regional
- Updates of member economies
- Updates on IMDRF member economies regulatory training/attachment
- IMDRF expert training
GOAL 4
To work in collaboration with related international organizations such as International Medical Device Regulators Forum (IMDRF), WHO, ISO, IEC.

• AHWP Representative in IMDRF, WHO, ISO/IEC, PAHO, APEC-LSIF
• Participation in WP
• Reporting/updates during AHWP meeting
PROPOSED WORK PROGRAM FOR GOAL 1

WORK PROGRAM 1
Develop framework for medical device regulations based

WORK PROGRAM 2
IDENTIFY HARMONIZATION ELEMENTS

WORK PROGRAM 3
IDENTIFY ELEMENT OF REGULATORY CONTROL

GOAL 1

WORK PROGRAM 4
IDENTIFY POLICY TO REGULATE PREMARKET, PLACE MENT & POST MARKET

WORK PROGRAM 5
DEVELOP REGULATORY DOCUMENTS

WORK PROGRAM 6
Programs on convergence and harmonization of medical device regulations in Asia and other continents
PROPOSED WORK PROGRAM FOR GOAL 2

WORK PROGRAM 1
IDENTIFY COMPETENCY GAPS AND NEEDS AMONG MEMBERS

WORK PROGRAM 2
REGULATORY COMPETENCY PROGRAM

WORK PROGRAM 3
CONSULTATION PROGRAM

GOAL 2

WORK PROGRAM 4
REGULATORY UPDATES

WORK PROGRAM 5
ATTACHMENT PROGRAMS

WORK PROGRAM 6
REGULATORY VISIT
PROPOSED WORK PROGRAM FOR GOAL 3

WORK PROGRAM 1
TRAINING NEED ANALYSIS

WORK PROGRAM 2
REGULATORY COMPETENCY PROGRAM

GOAL 3

WORK PROGRAM 3
ATTACHMENT PROGRAMS

WORK PROGRAM 4
TRAINERS/EXPERTS LISTING

WORK PROGRAM 5
TRAINING PROGRAMS

WORK PROGRAM 6
REGULATORY VISIT
PROPOSED WORK PROGRAM FOR GOAL 4 (EXISTING COLLABORATION)

WORK PROGRAM 1: COLLABORATION WITH IMDRF
WORK PROGRAM 2: COLLABORATION WITH APEC-LSIF
WORK PROGRAM 3: COLLABORATION WITH PAHO
WORK PROGRAM 4: COLLABORATION WITH WHO
WORK PROGRAM 5: COLLABORATION WITH IEC/ISO
Thank you