Implementation of Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"

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ASIAN HARMONIZATION WORKING PARTY

AHWP Strategic Framework

Objective & Milestones

- **Strategic Objectives:**
  - Continue the momentum built in the past
  - Provide a clear development plan and work targets towards the further enhancement of the capability of AHWP member economies in regulating medical devices, as well as the further strengthening of medical device regulatory harmonization and collaboration activities across the regions
  - Serves as a guiding principles for various AHWP activities

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AHWP Strategic Framework

Objective and Milestones (Cont.)

- **Milestones:**
  - Agreed and decision made by leaders at 16th Annual conference in Bali, Indonesia in 2011
  - Final draft posted at AHWP website in Oct 2012 for soliciting AHWP members comments
  - Comments reviewed and incorporated at Secretariat Meeting at KL, May 2013
  - Final endorsement at 18th Annual Meeting in Malaysia in 2013
  - WGs developed strategic framework implementation plan 2012 – 2014 in 1Q/2Q 2014
  - WGs progress reviewed at TC leaders meeting in Singapore in May 2014

AHWP Strategic Framework

Framework Elements

- **Element One: AHWP Membership Expansion**
  - Welcome any non-AHWP economic members who shows interest in participating
  - Invite current AHWP economic member who has experience and knowledge on medical device regulation to take leadership role at various levels (AHWP, AHWP TC, working groups) at AHWP
  - Secretariat office offer consistent support to member economies

AHWP Strategic Framework

- **Element Two: Training and Capacity building**

  - Focus on enhance knowledge on medical device, promote understanding of essential elements of medical device regulation, and promote international best practice

  - AHWP offer support to training and capacity building of members economies, in terms of financial and manpower

  - Identify priorities, partners of NGO, regional/international harmonization organizations (e.g. WHO, APEC, RAPS, MTLI, ARPA, and etc.)

  - Develop curriculum and review periodically

  - Promote utilization of advanced technology on training

AHWP Strategic Framework

- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**

  Harmonization in important areas based on availability of GHTF global regulatory model and AHWP guidance:

  - Harmonized definition of the term "medical device" (important in determining what and who are subject to regulation);
  - Registration of manufacturers, distributors, and importers and listing of medical devices marketed;
  - Adopt same risk-based classification of medical devices;
  - Single adverse event reporting and post-marketing surveillance system;
  - Single medical device nomenclature system;
  - Single quality management system requirements, and broader acceptance of quality management system audit report by authorized competent authorities ;
  - Acceptance of clinical evidence gathered, and evaluations conducted by, other AHWP/GHTF members ;
  - Acceptance of the same dossier (technical file) template for registration submission (e.g. the CSDT/STED format);
  - Recognition of 'recognized regulatory agencies' registration decisions to expedite evaluation process, etc.

AHWP Strategic Framework

- **Element Four: Enhance AHWP's Global Partnership**
  - Proactively approach international/regional organizations (e.g. IMDRF, APEC, ASEAN, WHO)
  - Identify important topics and establish mechanism for effective interaction and networking
    - Process of receiving from and providing feedbacks
    - Membership and representation
    - Joint strategic and roadmap development

AHWP Strategic Framework

Indicator of Success

- Increased inclusiveness of AHWP membership
- Enhanced awareness on the robust and effective medical device regulation in improving access, quality and use of medical device
- Adoption or adaption of the GHTF global regulatory model, AHWP and other harmonized international guidance and standards
- Enhanced collaboration among AHWP members, to improve and promote greater efficiency on regulation and use of resource: nomenclature, single post-market surveillance; multi-acceptance of QMS auditing report
- Enhanced global partnership, AHWP's participation at regional/global forums, and joint activities.

Implementation of AHWP Strategic Framework

- **Element One: AHWP Membership Expansion**
  - New application (Tanzania)
  - Potential new member economies (e.g. Bangladesh, etc.)
  - AHWP liaison membership (DITTA, GS1)
  - Non-member economy individuals joins WG membership and contribute (for further discussion)

Implementation of AHWP Strategic Framework

- **Element Two: Training and Capacity building**
  - Trainings conducted by WG1, WG1a, WG3 and WG4
  - WG6 collaborating with other WGs and STG:
    - Strategy/Direction: Developed in Sept 2014
    - Action Plan/budget: 2015
    - Partner with RAPS on curriculum development

Implementation of AHWP Strategic Framework

- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**
  - Development of **AHWP Playbook for Implementation of a Medical Device Regulatory Framework**
  - AHWP guidance documents
  - Restructure AHWP WG to:
    - Increase alignment of work of the AHWP Technical Committee to the current global trends in device regulations, facilitating coordination with related international organizations (IMDRF, APEC, WHO)
    - Position the AHWP TC to effectively respond and adapt to trends in medical device technology and regulatory strategies

Implementation of AHWP Strategic Framework

- **Element Three: Harmonization in Key Areas based on GHTF Principles and AHWP guidance**
  - Alignment with IMDRF work items:

IMDRF Work Items:	AHWP WGs/STG:
a) Standalone Medical Device Software Harmonization (SaMD)	a) WG3
b) A review of the NCAR system	b) WG2/SADS On-Line
c) Roadmap for implementation of UDI system	c) STG(N)
d) Medical Device Single Audit Program (MDSAP)	d) WG 6
e) IMDRF recognized standards	e) WG8
f) Regulated Product Submission	f) WG1&2

Implementation of AHWP Strategic Framework

- **Element Four: Enhance AHWP's Global Partnership**
  - Leadership participation and presentations at IMDRF MC meetings, ASEAN meetings, MEDTEC EUROPE conferences
  - Collaboration with AHC, DITTA, RAPS for training workshops at AHWP annual meetings
    - 1st AHWP-RAPS Joint Conference
    - APEC/AHC/AHWP Joint workshop on Medical Device Combination products in 2012
    - APEC/AHC/AHWP Joint workshop in 2014
  - WG collaboration with IMDRF, ISO TC210, ISO TC194
  - Collaboration with WHO
    - Pilot medical device regulatory awareness workshop in Cairo and Soudan in 2013
    - Medical Device Technical series: "Regulation Component"
    - To develop a "Joint 5 years training strategy/roadmap

Conclusion and Way Forward

- Much has been accomplished under the current AHWP leadership, WG leadership and members
- New three years (2014 to 2017) work plan need to be developed under new AHWP leadership and WG leadership in supporting the achievement of AHWP strategic framework **Towards 2020 - "The Foreseeable Harmonization Horizon"**
- Finalize and implement important projects:
  - AHWP Playbook for Implementation of a Medical Device Regulatory Framework
  - WHO/AHWP/APEC Training and capacity building strategy and work plan

THANK YOU