AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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

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Background and Objective of AHWP Strategic Framework

- **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

Background and Objective of AHWP Strategic Framework

- **Background:**

  - Agreed and decision made by leaders at 16th Annual conference in Bali, Indonesia
  - Draft developed and discussed at February AHWP leaders' meeting
  - Revision based on comments received and circulation for leaders' comments between March to June
  - Draft endorsement by AHWP leaders at AHWP TC meeting in June, 2012
  - Further revision between June to Oct, 2012
  - Final draft posted at AHWP website in Oct 2012 for soliciting AHWP members comments

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

Framework Elements

- **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

Framework Elements

- **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.

Framework Elements

- **Element Four: Working Alongside with APEC and ASEAN to expand beyond regional blocks**
  - APEC strategic framework on regulatory convergence by 2020 was endorsed by 21 economic members in 2011
  - ASEAN will implement AMDD in 2015 to harmonize medical device regulation
  - With common member economies, such efforts will be further leveraged, for example, joint programs on training and capacity building

Framework Elements

- **Element Five: Enhance AHWP's Global Presence**

  – Proactive reach out to international originations, global leaders and experts

  – Establish mechanism for effective interaction and networking:
    - Process of receiving from and providing feedbacks
    - Membership and representation
    - Joint strategic and roadmap development

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 embers, to improve and promote greater efficiency on regulation and use of resource: nomenclature, single post-market surveillance; multi- accetpance of QMS auditing report
- Enhanced global partnership, AHWP's participation at regional/global forums, and joint activities.

Next Step:

AHWP Strategic Framework can be found at:
http://www.ahwp.info/index.php?q=node/297

Your review and comment before Feb 4, 2013 is highly appreciated!