Report and Overview of AHWP TC of the Past Term: **Key Milestones**

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AHWP TC Milestones (2012 – 2014)

- Participation in IMDRF
- Participation in ISO / TC 210
- AHWP Strategic Framework
  The Foreseeable Harmonization Horizon

**2012**
- Work Plan & Targets Set for Working Groups & Special Task Group
- AHWP TC Milestones (2012 – 2014)
  - 13 Technical Documents Developed (over 3-year term)
  - Contributed to 3 Joint International Events
    - 2012 APEC-AHC-AHWP Joint Workshop - MD Combi Products
    - 1st AHWP-RAPS Joint Conference
    - 2014 AHC-AHWP Joint Workshop

**2013**
- Establishment of AHWP TC Advisory (10 experts)
- Liaison members: DITTA, GS1
- Establishment of Working Group 7 – Standards

**2014**
- Refinement of AHWP TC Working Group Structure
- Finalization of AHWP TC Playbook

Contributed to 3 Joint International Events

- 2012 APEC-AHC-AHWP Joint Workshop - MD Combi Products
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AHWP Strategic Framework

Guide for various AHWP activities which contributes to the achievement of AHWP’s mission: to promote regulatory harmonization in order to enhance patient safety and increase access to safe, effective and clinically beneficial medical technologies across AHWP member economies.

4 Framework Elements

- AHWP Membership Expansion
- Training and capacity building
- Harmonization in Key Areas based on GHTF Principles and AHWP guidance
- Enhance AHWP’s Global Partnership
12 Technical Documents Developed

Pre-market
• Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format
• Essential Principles of Safety and Performance of IVD Medical Devices
• AHWP Regulatory Framework for IVD Medical Devices
• White Paper on Medical Device Software Regulation - Software Qualification and Classification

Quality management system
• Guidance on the Quality Management System for Medical Device Distributor
• Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers (Part 1 - 5)
• Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

Post-market
• Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative
• Adverse Event Reporting Timelines Guidance for Medical Device Manufacturer and its Authorized Representative
• Medical Device Adverse Event (AE) Report Form
• Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions

Playbook
• Playbook for Implementation of a Medical Device Regulatory Framework
International TC Meetings

18th, 19th & 20th AHWP TC Main Meetings
AHWP TC Leaders & Advisors Meetings

2012 APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products
Chinese Taipei Nov 4, 2012

AHWP & RAPS Joint Conference
2-3 December 2013 • Selangor, Malaysia

2014 AHWP
AHC-AHWP JOINT WORKSHOP,
THE 18th AHWP TC MEETING &
THE 19th AHWP ANNUAL MEETING
NOV. 18-21, 2014
VISTA HALL, SHERATON GRANDE WALKERHILL, SEOUL, KOREA
Thank You