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

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20 Nov 2014

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

AHWP TC Milestones (2012 – 2014)

- Work Plan & Targets Set for Working Groups & Special Task Group
- Participation in IMDRF
  Participation in ISO / TC 210
- AHWP Strategic Framework
  The Foreseeable Harmonization Horizon
- Refinement of AHWP TC Working Group Structure
- Finalization of AHWP TC Playbook

2012 | **2013** | **2014**

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

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

13 Technical Documents Developed (over 3-year term)

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

Thank You