



Update from APEC LSIF-RHSC

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Priority Work Areas (PWAs)

- Medical Device Vigilance
(Ministry of Food & Drug Safety, Rep of Korea)

Project Title:

Roadmap to Promote Convergence for Medical Device Vigilance (MDV)

- The roadmap of medical device vigilance was endorsed during APEC - SOM3 meeting in Lima-Peru on 15-18 August 2016

The Goal of Medical Device Vigilance Roadmap

- 1. Promoting harmonization and advancement of medical device vigilance activities** between APEC economies
- 2. Contributing to active medical device vigilance system** within the member of APEC Economies through workshop and training programs
- 3. Promoting protection of public health** based on the evaluation and dissemination of the MDV safety information

Specific Activities and Time Frame

STEPS

ACTIVITIES

Step 1 : Gap Analysis
(2016-2017)

- Organize working group
- Perform the gap analysis of MDV in APEC Economies
- Hold a workshop

Step 2 : Training
/Workshop (2017-2019)

- Develop training curriculum for regulatory authorities
- Hold trainings and workshops

Step 3 : Assessment
Training and
Recommendation
(2019-2020)

- Share assessment results of MDV training outcomes
- Revise and update MDV training program
- Provide recommendation on MDV

Summary of Significant Activities

1. Develop survey item of gap analysis of MDV system in APEC Economies (May 2016)
 - total of 13 survey items were selected as follow AE reporting comparison items that GHTF used to survey on 2002, annual number of AE reporting and government activities to collect and analyze AEs
2. Organize a working group of MDV roadmap (June 2016)
 - 10 Expert of 7 APEC Member Economies
3. Announce the APEC Harmonization Center (AHC) Pharmacovigilance and Medical Device Vigilance workshop (July 2016)
 - Medical Device Vigilance workshop was held on 5th of September 2016 in Seoul, Rep of Korea

2016 AHC-Medical Device Vigilance Workshop

- Workshop was held on 5th Sept 2016
- Venue: Novotel Ambassador Hotel, Seoul – Republic of Korea
- The composition of Workshop module:
 1. Session I: Introduction of IMDRF/GHTF, AHWP MDV guidance and activities
 2. Session II: Current status and management system on AE Reporting in 5 Countries
 3. Session III: AE Reporting system in Industry
 4. Session IV: Path forward and next step of MDV Roadmap (panel discussion)

Assessment of “2016 AHC MDV workshop” to reflect its outcome for next year workshop training curriculum development

Plan for Future Activities

1. From Oct 2016 to April 2017 : Gap analysis of MDV in APEC economies through investigation and comparison of the current status of MDV in each economy. Hopefully on April 2017 final reports will be issued and shared.
2. From April 2017 to November 2017: Develop training curriculum for each economy's regulatory authorities based on IMDRF/GHTF/AHWP guidance documents with working group



ASIAN HARMONIZATION
WORKING PARTY

THANK YOU