



ASIAN HARMONIZATION WORKING PARTY

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Priority Work Areas (PWAs)

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

Project Title:

Roadmap to Promote Convergence for
Medical Device Vigilance

- developed a Concept Note for Medical Device Vigilance

Roadmap to Promote Regulatory Convergence for Medical Device Vigilance

1. To promote harmonization and advancement of the vigilance activities within the APEC region by suggesting harmonized and appropriate procedure
2. To contribute to active vigilance within the member countries and establish global vigilance system through forums and training programs
3. To promote public health protection and virtuous cycle of information use in medical device development and improvement by disseminating safety information

Roadmap to Promote Regulatory Convergence for Medical Device Vigilance

1. Conduct annual workshop/training by developing training programs in order to stabilize the vigilance system of each country. That is, we will contribute to vitalization of post-market management of medical devices in each APEC country, eventually, establishing international medical device vigilance system.

Roadmap to Promote Regulatory Convergence for Medical Device Vigilance

(i) 2016-2018: Assessment

- **Gap Analysis (2016 – the first half of 2017)**
- Compose a working group for regulatory harmonization of adverse event report system and measures, and etc., and analyze gap by researching adverse event management system and its current status in each APEC country
- Activities of IMDRF and AHWP TC WG, research and review of guideline on adverse event management, report form, and etc.(including activities and documents of GHTF Study Group 2), review of WHO published medical device regulation

Roadmap to Promote Regulatory Convergence for Medical Device Vigilance

- **Safety alerts dissemination Study (the second half of 2017 - 2018)**
- Propose the procedure for efficient vigilance based on the Gap analysis result
- Conclude safety alerts dissemination procedure between APEC countries and report form by reviewing exchange criteria and report form of AHWP's SADS(Safety Alerts Dissemination System) and IMDRF's NCAR(National Competent Authority Report)

Training/Workshop

- **(ii) 2018–2020: Training/Workshop**
- Design training program and workshop contents to disseminate APEC procedure on adverse event report to regulatory authorities and experts from medical device industry
- Provide workshops periodically and annual training program
- Determine procedure for adverse event management and information exchange form between APEC countries through evaluation of training and workshops
- Based on the vigilance, the training and workshop shall include contents/topics as follows;

Training/Workshop topics

- Difference in vigilance between International Medical Device Regulators Forum (IMDRF) and APEC member countries
- Definition of adverse event, and standard, form and system of adverse event report
- Terminology of adverse event report and study on adverse event code system
- Management of adverse event report database
- Methods to assess classification of adverse event causes in each APEC country
- Investigation of adverse event causes and procedure or model for decision of causation assessment

Training/Workshop topics

- Current status of management of tracking system for high-risk implantable medical devices
- Standard or model for risk assessment by product items
- Standard for risk assessment of medical devices with potential risk
- Study on prediction of adverse event: Examples of case study of individual product item
- Product improvement and R&D based on adverse event monitoring: Examples of case study of individual product item
- Best practices of medical device vigilance training program
- Methods to exchange safety information within the APEC region

Action item on the Concept Note

Member countries to provide comments
on the concept notes



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THANK YOU