

APEC Concept Note

Project Title:	Roadmap to Promote Regulatory Convergence for Medical Device Vigilance
Source of funds (Select one): <input type="checkbox"/> Operational Account <input type="checkbox"/> TILF Special Account <input type="checkbox"/> APEC Support Fund	
Committee / WG / Sub-fora / Task-force:	Regulatory Harmonization Steering Committee (RHSC)
Proposing APEC economy:	Korea
Co-sponsoring economies:	<i>(to be confirmed)</i>
Expected start date:	March 2016
Expected completion date:	December 2020
Project summary: Describe the project in under 150 words. Your summary should include the project topic, planned activities, timing and location: <i>(Summary must be no longer than the box provided. Cover sheet must fit on one page)</i>	<p>The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incident elsewhere. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents. The vigilance system is not confined only to safety issue, and is included in a virtuous cycle project which is utilized as information to develop new medical devices and its improvement. The project titled “Roadmap to Promote Regulatory Convergence for Medical Device Vigilance” will carry out harmonization of “medical device vigilance” by analyzing the management system (including collection, analysis, assessment, and corrective action) of adverse event of APEC economies and current status of the vigilance system. We will conduct training based on IMDRF and GHTF Guidance Documents in order to stabilize the vigilance system of APEC economy. Medical device vigilance roadmap will contribute to vitalization of post-market management of medical devices in each APEC economies, eventually, establishing international medical device vigilance system.</p>
Total cost of proposal: <i>(APEC funding + self-funding)</i> USD \$	Total amount being sought from APEC (USD): \$ - By category: <i>Travel:</i> \$ - <i>Labor costs:</i> \$ - <i>Hosting:</i> \$ - <i>Publication & distribution:</i> \$ - <i>Other (interactive website design/construct et al): \$ -</i>

Project Overseer Information and Declaration:

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As Project Overseer and on behalf of the above said Organization, I declare that this submission was prepared in accordance with the **Guidebook on APEC Projects** and any ensuing project will comply with said Guidebook. Failure to do so may result in the BMC denying or revoking funding and/or project approval. I understand that any funds approved are granted on the basis of the information in the document’s budget table, in the case of any inconsistencies within the document.

Name of Project Overseer

Date: Aug 2015

Project Synopsis

1. Relevance: Why should APEC undertake this project? What problem or opportunity will the project address and why is it important?

The medical device vigilance regulation is an integral part of a post-market surveillance system to improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incident elsewhere. APEC member economies implement the post-market adverse event management system based on IMDRF and GHTF Guidance Documents, but an institution in each economy differs in each economy: definition of adverse event, mandatory reporters, report deadline, standard terminology, structure of standard code, adverse event report form, categorization of risks, causing assessment, follow-up measures, etc. are different in each economy, and safety information sharing system between economies does not exist.

If a same device is used in the member economies, the adverse event shall be immediately shared within the member economies, preventing serious damage caused by adverse event and protecting patients and customers without borders. With the medical device vigilance project, APEC member economies shall actively communicate with each other to harmonize vigilance standard, properly collecting, analyzing, assessing and sharing safety information of all marketed medical devices within the APEC region.

2. Objectives: Describe the 2-3 key objectives of the project. (e.g., to... create a framework...; ensure participants will be able to...; share experiences...; enhance understanding...; develop recommendations...; build interest...; revise strategies... etc.)

- To promote harmonization and advancement of the vigilance activities within the APEC region by the vigilance system based on IMDRF and GHTF Guidance Documents
- To contribute to active vigilance within the member economies through forums and training programs for the vigilance system based on IMDRF and GHTF Guidance Documents
- To promote public health protection and virtuous cycle of information use in medical device development and improvement by disseminating safety information

3. Alignment: Describe how the project will help achieve APEC's key priorities and meet your forum's work-plan or medium-term plan.

This project has been initiated from suggestion for promoting medical device vigilance roadmap in the general assembly of APEC Philippines 2015, and supports the APEC RHSC's strategic framework aiming at the 2020 regulatory harmonization of medical products. The project will propose reasonable measures to harmonize adverse event management system in the member economies, and efficiently disseminate and share safety information, satisfying APEC's expectation for regulatory harmonization.

4. Methodology: How do you plan to implement the project? In this section, address:

- Timeline: Project timeline and dates for key activities and deliverables
- Stakeholders: Beneficiaries and stakeholders (APEC & non-APEC). How they will be engaged
- Previous projects/activities: How do we design previous projects and activities, and current proposals, while avoiding duplication?
- Communication: How do we plan to disseminate the results or benefits of this project to others?

Timeline: This project will be conducted from March, 2016 to December, 2020.

(i) 2016: Gap analysis

- Compose a working group for regulatory harmonization of adverse event report system and measures, etc., and analyze gap by researching adverse event management system and its current status in each APEC economy
- Review activities of IMDRF NCAR Working Group, GHTF Study Group 2 and AHWP TC Working Group 4
- Review guidance for adverse event reporting for medical device and national competent authority report exchange criteria and report form
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(ii) 2017–2019: Training/Workshop

- Design training program and workshop contents to disseminate IMDRF and GHTF Guidance Documents on adverse event report to regulatory authorities and experts from medical device industry
- Provide workshops periodically and annual training program
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- Based on the vigilance systems of IMDRF and GHTF Guidance documents, the training and workshop shall include contents/topics as follows;

- Difference in vigilance between IMDRF Guidance and APEC economies regulation
- 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 economies
- Investigation of adverse event causes and procedure or model for decision of causing assessment
- 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 the national competent authority report (NCAR) within the APEC region

(iii) 2020: Assessment of Training/Workshop

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- Expand regional trainings and workshops to vitalize the vigilance
- Secure programs and a pool of lecturers and experts to disseminate vigilance standard
- Discuss to exchange the national competent authority report (NCAR) based on IMDRF and GHTF Guidance documents between APEC member economies (non-IMDRF management committee regulators)
- Propose direction for future regulatory harmonization of research and documentation of excellent cases of the vigilance

Stakeholders:

Beneficiaries of the vigilance will include regulatory authorities, medical device companies participating in the adverse event report, and healthcare professionals and customers. Concerned

members from LSIF and RHSC, and experts from industry, academy, regulatory authority and medical institutions will participate in this project. Concerned people who are well aware of post-market management system should share their experiences and knowledge with others. On the other words, concerned people who do not have experience in this management system should learn those experience and knowledge, trying to make the post-market medical device management system established and expanded.

Previous projects/activities:

This project has been initiated from suggestion for promoting medical device vigilance roadmap in the general assembly of APEC Philippines 2015. The APEC RHSC has already promoted roadmap for pharmacovigilance and biopharmaceuticals to harmonize medical product regulation.

To harmonize vigilance and share adverse event information between APEC economies will be a measure to integrate their regulation and promote their economic growth

Communication

- (i) The result of this project and benefits will be summarized in e-report form. All documents are presented in PDF format and will be listed on the website of APEC RHSC and its related APEC economies.
- (ii) The result and assessment report will be presented to the APEC RHSC.
- (iii) The stakeholders for medical device regulatory harmonization will communicate through e-mails and agenda board.