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Economic Cooperation**



IMDRF International Medical
Device Regulators Forum

Updates of APEC Life Science and Innovation Forum Regulatory Harmonization Steering Committee (LSIF-RHSC)

LIMA-PERU, 23-25 FEBRUARY, 2016

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Project Title:

Roadmap to Promote Convergence for
Medical Device Vigilance

- Developed a Concept Note for Medical Device Vigilance



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Roadmap Outline In Medical Device Vigilance



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- **OBJECTIVES:**

1. Promoting regulatory harmonization and development in medical device vigilance within the APEC Region
2. Activating medical device vigilance among the APEC economies by providing training to regulators
3. Secure safety and improving quality via disseminating safety information

- **METHOD:**

- ✓ (STEP 1), Gap analysis by researching Adverse Event Management System of each APEC Economies
- ✓ (STEP 2), Training expert from regulatory authority and industry regarding adverse events management system.
- ✓ (STEP 3), Review the training outcomes and set recommendations



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Review

the Progress of Project in 2015



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- **The 1st RHSC Meeting in Clarck, Philippines :**
Confirming the implementation of regulatory harmonization for medical device vigilance.
- **The 3rd RHSC Meeting in Cebu, Philippines :**
Presentation and discussion of the roadmap concept note regarding the medical device vigilance (August 2015):
 - Suggestion for roadmap revision
 - Training based on IMDRF/GHTF guidelines
 - Requirement for confidentiality agreement between APEC economies to exchange National Competent Authority Report (NCAR)
 - The issue to separate the roadmap of Medical Device Vigilance from Roadmap of Pharmaceutical Vigilance.
- **Modification of Concept Note:**
Asking for comments for modified concept note via e-mail by RHSC Secretariat (from Dec 2015 – feb 2016)



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Changes in Concept Note of Medical Device Vigilance



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No	Topic Changes	Before Revision	After Revision	Remark
1	Training based on the IMDRF/GHTF guidance	Training by establishment of new guideline for medical device vigilance and exchanging NCAR	Training on the basis of existing guidance from IMDRF/GHTF and AHWP <ul style="list-style-type: none"> No requirement for the development of new guidance 	International regulatory harmonization and Prevention the duplication work.
2	Shorten the timeline of medical device vigilance roadmap	Timeline from 2016 until 2022	Timeline from 2016 until 2020	No requirement for development new guidance because using the existing international guidance.
3	Confidentiality agreement between APEC Economies to exchange NCAR	<ul style="list-style-type: none"> IMDRF Guidance Published in 2015, provide the criteria, procedure form and requirements involving confidentiality when NCAR is shared. (IMDRF/NCAR WG N14:2015) Training plan for exchanging NCAR (from 2017-2019) and discuss about exchanging NCAR among the APEC economies based on the guidelines of IMDRF and AHWP (by 2020) 		

PLAN FOR 2016

- **Gap analysis :**
 - Establishing of 11 items for investigation including reporting time, criteria, form, procedure of report so on based on GHTF document in 2002 (GHTF/SG2/N6 R3:2002)
 - Comparison of current status in the five selected economies of APEC.
 - ✓ **Timeline in Details :**
 - ✓ Establishment of survey questioner (≈ April 2016)
 - ✓ Recruiting nations for participating in investigation (≈ May 2016)
 - ✓ Preparation of current status and data in each economy (≈ Oct 2016)
 - ✓ Reporting for the comparison of the current status (≈ December 2016)
 - ✓ Inquire view point from each member of APEC. (≈ March 2017)
 - ✓ Publication of comparison report (≈ April 2017).

- **International workshop for regulatory harmonization in medical device vigilance:**
 - Presentation and discussion of investigation result from each economies.
 - Introduction of IMDRF/GHTF and AHWP guidance.
 - Presentation of manufacturer's adverse events management system.
 - ✓ **Timeline in Details :**
 - ✓ organizing workshop and inquiry of workshop (≈ April 2016)
 - ✓ Recruiting speakers and attendees of workshop (≈ May 2016)
 - ✓ Informing a workshop (≈ June 2016)
 - ✓ Holding a workshop (≈ September 2016)
 - ❖ Medical device vigilance and pharmaceutical vigilance will be held concurrently

Update on the PWG Pharmacovigilance and Medical Device Vigilance Concept Note

1. Concept Note on medical device vigilance approved
2. Pharmacovigilance and medical device vigilance to be merge into one roadmap, and will be presented on next APEC-RHSC Meeting (SOM-3) in August 2016
3. Two COE Pilot of Phamacovigilance and Medical Device will be held by KIDS (Korea) in September and PMDA (Japan) to be determined



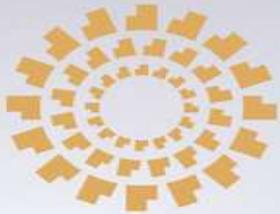
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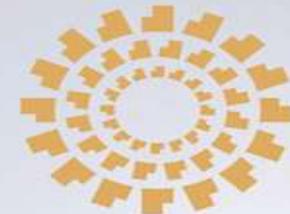
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Life Sciences and Innovation Forum
Regulatory Harmonization Steering
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Meeting

Lima, 23-25 February 2016



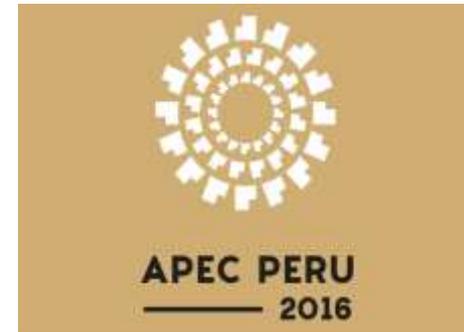
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