

# ***Promotion of Good Submission Practice in Asia***

April 5<sup>th</sup>, 2017

6<sup>th</sup> Asia Partnership Conference of Pharmaceutical Associations

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# Promotion of Good Registration Management

**Realize early access to new medicines for peoples in Asia**

**Enhance efficiency of NDA review**

**Good Registration Management  
(GRM)**

**Good Review  
Practice  
(GRevP)**

**Good Submission  
Practice  
(GSubP)**

**Make proposals to support  
facilitation of GRevP**

**Improve quality of submission  
and its management**

- **Further improvement in transparency, predictability and timeliness of review by facilitating communication** 6th APAC, Apr 5th, 2017
- **Reduced number of critical deficiencies**
- **Decrease of rejections**

**APAC  
Position  
Paper**

**APAC  
GSubP  
Guideline**

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## *RA-EWG's Activities in FY2016*

- **2016 APEC GRM Regulatory Science CoE Pilot Workshop**
  - Common Session
  - Applicant session
- **Task A**
  - Progress Report
  - JPMA's activities
- **Task B**
  - Analysis Report
  - Draft infographic summary for the common six topics in Asia

## *RA-EWG's Plan in FY2017*

# Historical background of GRM

- 2011  APEC RHSC started implementing GRevP topic
  - Champion authority: TFDA
- 2014  APAC advocated GRM concept and started GSubP activities
  - GSubP was proposed as new topic in APEC RHSC
- 2015  WHO adopted GRevP Guidelines as Annex 9 of the Technical Report Series No. 992, 2015
  - [http://apps.who.int/iris/bitstream/10665/176954/1/9789240693968\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/176954/1/9789240693968_eng.pdf?ua=1)
  - GRM was adopted by APEC RHSC as combined topic of GRevP & GSubP
    - Champion authorities: TFDA & PMDA
- 2016  GSubP Guideline prepared by APAC got the endorsement of APEC RHSC
  - [http://apac-asia.com/images/achievements/pdf/5th/2\\_APEC\\_RHSC%20Endorsed%20GSubP%20Guideline.pdf](http://apac-asia.com/images/achievements/pdf/5th/2_APEC_RHSC%20Endorsed%20GSubP%20Guideline.pdf)
  - GRM CoE Pilot training program started**

# 2016 APEC GRM Regulatory Science CoE Pilot Workshop (Nov 15<sup>th</sup> – 17<sup>th</sup>, 2016)

**2016 APEC**  
Good Registration Management (GRM)  
Regulatory Science Center of Excellence Pilot Workshop

**Save the Date** 2016.11.15-11.17  
Taipei / Chang Yung-Fa Foundation

**Program Overview**  
A 3-day program focusing on Good Review Practices (GRevPs), Good Submission Practices (GSubPs), and GRM with lectures, group discussions and applied case studies. The program includes Common Sessions, Reviewer-Specific Sessions, and Applicant-Specific Sessions.

**Target Audience**

- 1) Regulatory professionals from regulatory authority or industry,
- 2) with at least three years of hands-on experience in the management of regulatory reviews or regulatory submissions,
- 3) who are interested in understanding guidelines such as GRevPs or GSubPs,
- 4) who are actively involved in training of regulatory staff within their organizations

**Registration**

- Available from 14 September to 14 October via e-mail ONLY. No registration fee required
- Pre-registration is required by submitting application form with information on hands-on experiences in the management of regulatory review or submission. Please contact rapstaiwn@tcfst.org.tw for the form.
- Limited seats are available (approx. 50 in total; 25-30 each for Reviewer-and Applicant-Specific Sessions)
- Priority will be given to the nominated representatives of APEC member economies

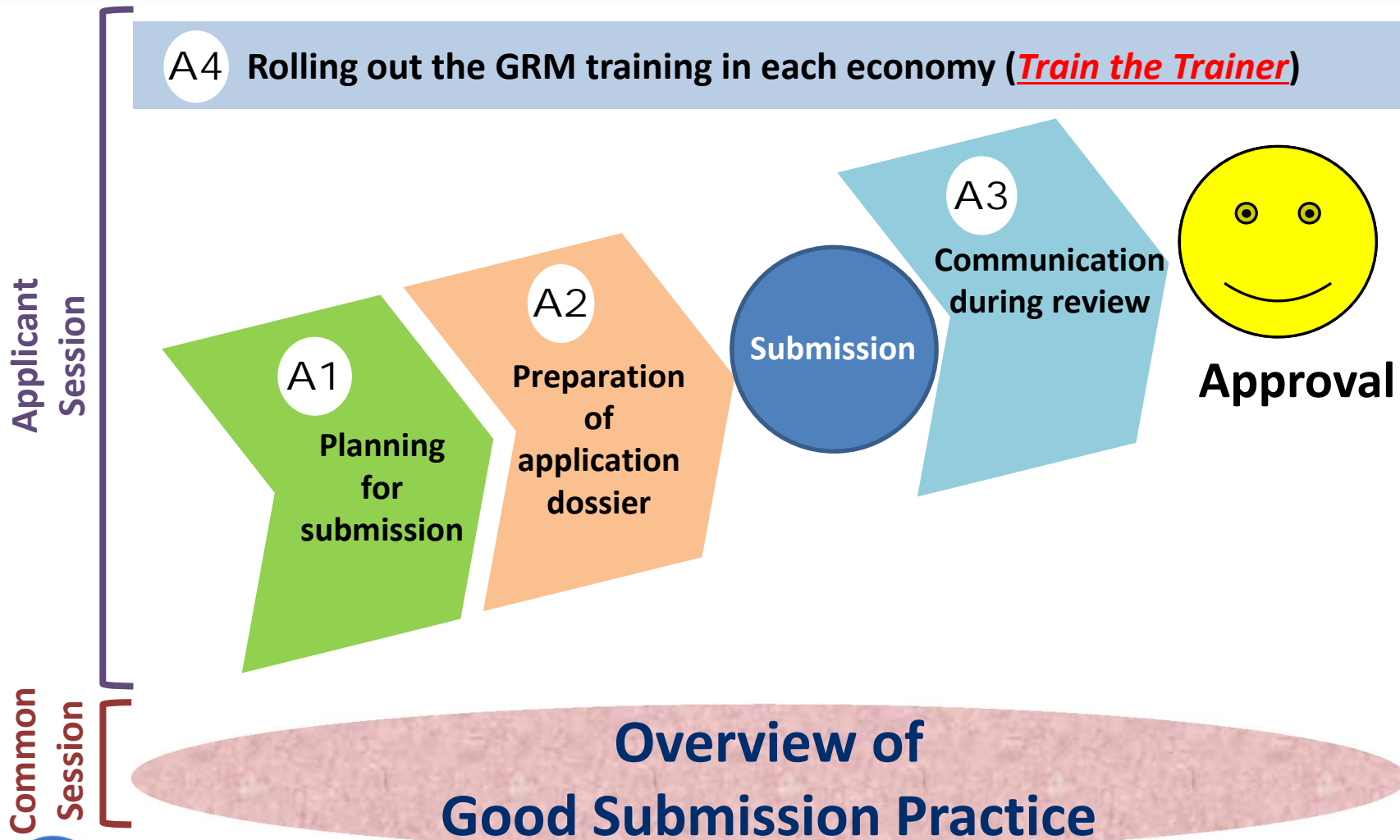
**Travel & Accommodation**  
Funding for travel eligible economies may be available.

**Contact information**  
Dr. Yu-Hua Huang Email: yhuang@tcfst.org.tw  
RAPS Taiwan Chapter Email: rapstaiwn@tcfst.org.tw

Logos: APAC, PMDA, FDA, AHC, RAPS

Day1	Day 2		Day 3	
<p><b><u>Common Session</u></b> Basic concept of GRM</p> <p>Overview of Good Submission /Review</p> <p>Effective Communication for GRM</p>	<p><b><u>Reviewer Session</u></b> Managing the review</p> <p>Communication Fundamentals and case studies</p>	<p><b><u>Applicant Session</u></b> Planning of Application</p> <p>Prep of Application Dossier</p>	<p><b><u>Reviewer Session</u></b> Review Critical thinking</p> <p>Conducting the review</p> <p>Rolling out GRM training in each economy</p>	<p><b><u>Applicant Session</u></b> Communication during review period</p> <p>Rolling out GRM training in each economy</p>
			<p><b><u>Common Session</u></b> Panel Discussion on Competency</p>	

# Curriculum for Good Submission Practice



# Participants for Applicants Session

## Trainers/Facilitators

<b>Trainer</b>	Japan	JPMA	6
	Singapore	SAPI	3
		CORE	2
<b>Facilitator</b>	Thailand	PreMA	2
<b>Secretariat</b>	Japan	JPMA	1
<b>Total</b>			<b>14</b>

*9 APEC member economies  
10 APAC member associations*

## Trainees

China	RDPAC	3
Hong Kong	HKAPI	2
Japan	JPMA	2
Korea	KPMA	1
	KRPIA	1
Malaysia	PhAMA	2
Philippines	PHAP	3
Singapore	SAPI	3
Taiwan	IRPMA	3
	Others	6
Thailand	PreMA	3
<b>Total</b>		<b>29</b>



# Phots

**Applicant  
Session**  
*Case Studies  
Gr. Discussions  
etc.*



## Common Session Lectures





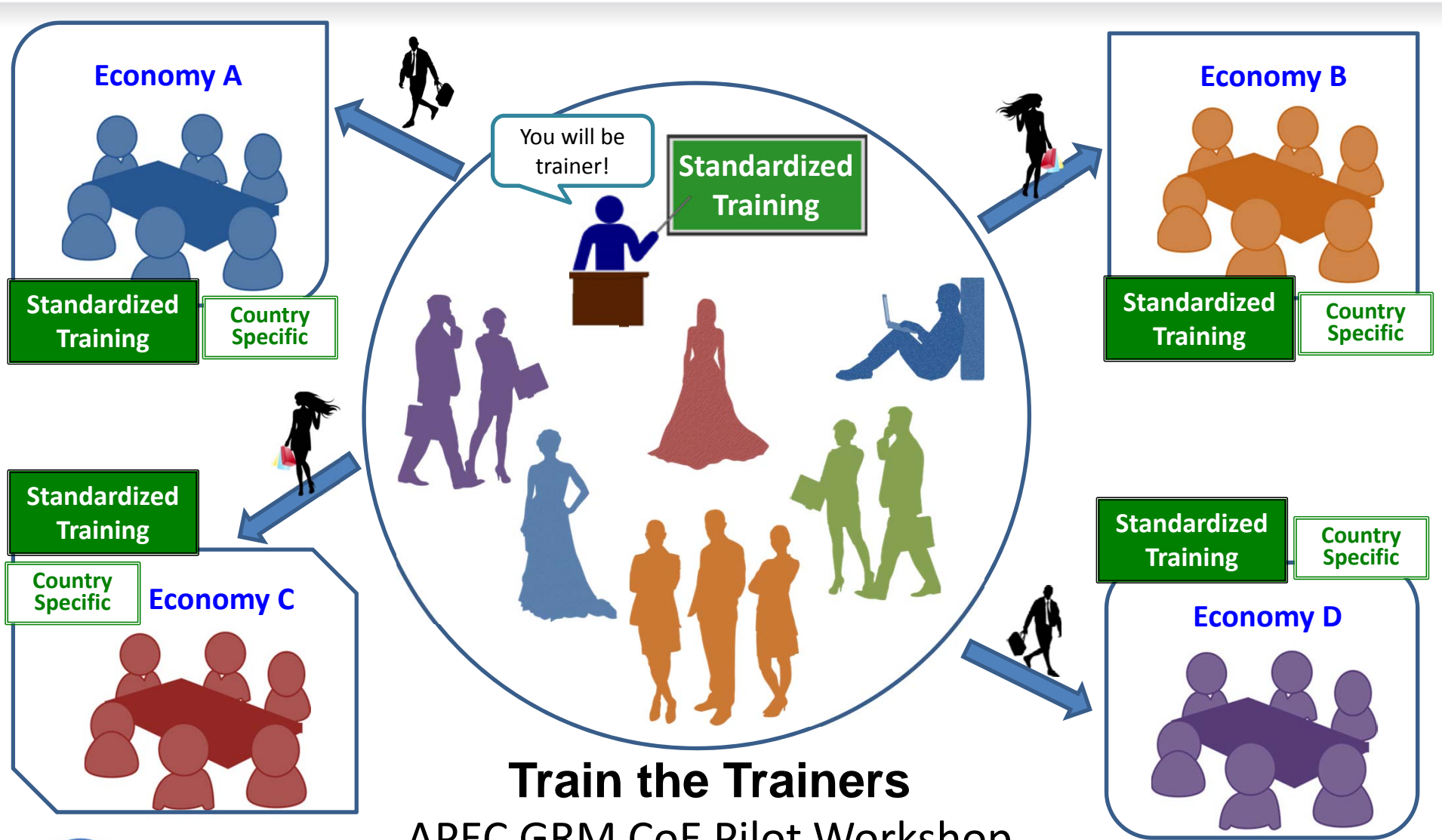
# Feedback from Trainees for Applicant Session

- **More than 4 in 5-point scale evaluation**
- **Topics/presentations most useful to trainees**
  - Topics
    - Communication
    - Planning for submission
    - QC & Dossier Preparation
    - All topics
  - Program/Content
    - Case study & group discussion are very good
    - The tools, the exercises
- **Topics/areas trainees to see in the future GRM workshop**
  - Interactive sessions between reviewers and applicants
  - Effective communication
  - More case studies: implementation of GRM, submission to regulatory authorities among Asia/US/EU
  - Others
    - tools for improving quality of submissions, project management, risk management, critical thinking

➡ **Successfully Finished!!**

➡ **Ideas for Further Improvement**

# Train the Trainers



**Train the Trainers**  
APEC GRM CoE Pilot Workshop

# *Plan of Training in Each Economy*

## *Survey summary after APEC GRM CoE Pilot Workshop within APAC member associations*

- 7 associations in APAC are **positive** about local training in their economy at this moment
- Key factors for implementation
  - **Endorsement by their authority** and/or **Collaboration with their authority**
  - Availability of trainers, training materials
    - e.g. number of trainers, local language

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## ***RA-EWG's Plan in FY2017***

# Task A

## *Make Proposal to Support Facilitation of GRevP*

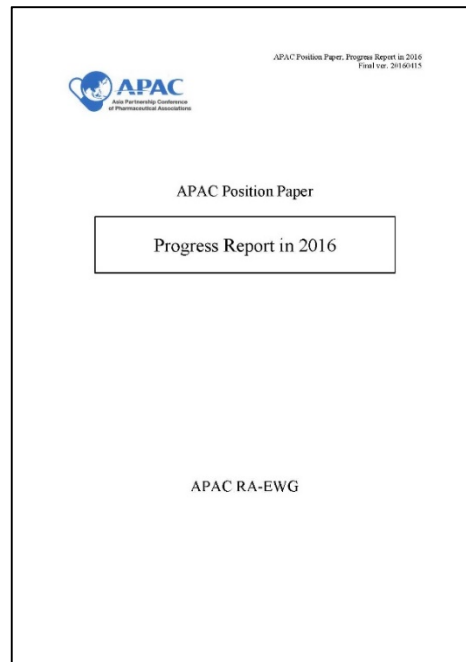
### APAC POSITION PAPER IN 2015

- #1: Establishing structured framework to support ***regulatory consultation***
- #2: Facilitating ***transparency to review policy, standards, draft regulations, guidelines and new initiative from regulatory authority***
- #3: Facilitating transparency to ***review process and status***
- #4: Facilitating ***collaborative training program and workshop*** between the regulatory authorities and industry
- #5: Facilitating ***generation of review report in English***

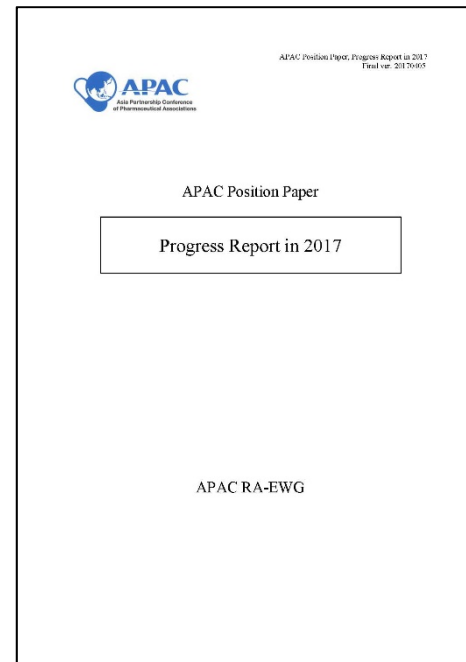
# Task A Progress Report

*APAC member associations have picked up topics of focus in their economy for further discussion with their authority*

## 5<sup>th</sup> APAC in 2016



## 6<sup>th</sup> APAC in 2017



***Further improvement in transparency, predictability and timeliness of review by facilitating communication***

# ***Task A: JPMA's key activities***

## **FOCUSED TOPIC**

Facilitating Generation of Review Report in English

### ***FY2015***

- Review of status associated with generation of Review Report in English

### ***17 Mar, 2016***

- Initial discussions with PMDA

### ***5 - 22 Dec, 2016***

- Questionnaire within JPAM

### ***25 Jan, 2017***

- Discussion with PMDA

### **Expectation effect**

Utilization/Promotion of PMDA's Review Report in English for developing our innovative medicines in Asia

# *JPMA's key activities for Task A (Cont'd)*

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## *Summary of Questionnaire within JPMA*

- Intended respondents
  - International Affairs Committee (Mainly Asia group)
  - Regulatory Affairs Committees
- Summary Results
  - Hope to;
    - Know candidates of translation earlier for planning development in Asia
    - Consult with PMDA about priority of candidates/period for translation



# *JPMA's key activities for Task A (Cont'd)*

## *Discussion with PMDA*

- PMDA's basic concept for Review Report in English
  - Demonstrate transparency of review process for especially innovative medicines to not only Japan but also globally
- Next action to be taken in FY2017
  - Survey products which have Review Report in English would align Industries' expectation



About PMDA



Find Review reports, PI

<https://www.pmda.go.jp/english/index.html>

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## ***RA-EWG's Plan in FY2017***

# Task B

## *Promote regulatory convergence of NDA requirements in Asia*

- Convergence of NDA Requirements Proposal Document & Fact Sheet (2014)
  - Brief overview of selected topics (Fast-Track, Clinical Data, DMF, Pharmacopoeia, Package Insert, etc.)
- Analysis Report (2013, 2014, 2015, 2016 & **2017**)
  - Identification and Clarification of the Differences in Regulatory Requirements between Asian Economies

# Task B: Draft infographic summary

## Draft infographic summary for the common six topics in Asia

- To Disseminate Discussion of Regulatory Convergence in Other Platforms

**Draft image of infographic**

Progress of Regulatory Convergence		
Topic	Goal	Hurdle/Challenge
<b>Session 1</b> GRM to strengthen product registration system in Asia	GRM as well known and wide practiced concept for efficient and high quality product registration process	Rapid dissemination of concept to stakeholders
<b>Session 2</b> International Council for Harmonisation (ICH)	Timely implementation of ICH guidelines as technical review standard throughout Asia	Slow implementation in interpretation
<b>Session 3</b> Global GMP Inspection Practice	Increase in number of PIC/S member countries in Asia Progress in work sharing, e.g. co-inspection, MRA	Limited number of countries Slow bilateral cooperation
<b>Session 4</b> Life Cycle Management	Efficient LCM realized by adoption & implementation of new concepts such as QbD, ICH Q12	Challenging efficient regulatory approval
<b>Session 5</b> Regulatory convergence and promotion of work sharing in ASEAN	Consistent implementation/interpretation of ACTR with adequate harmonization with ICH	Diversified regulatory interpretation Country specific differences
<b>Session 6</b> Acceleration of the Regulatory Review Process for Innovative Medicines	Consistent and workable accelerated review mechanism established widely in Asia Proper implementation of risk management system	Slow/limited accelerated review Limited regulatory resources

E.g.)

9<sup>th</sup> ARC (<http://www.9th-arc.org/>)

### ➤ Date & Venue

- ✓ April 6<sup>th</sup> – 7<sup>th</sup>, 2017
- ✓ Tokyo Conference Center Shinagawa

### ➤ Session topics

- ✓ GRM, ICH, GMP inspection, LCM/Technical Variation, ASEAN Convergence, Regulatory Review System

### ➤ Closing panel discussion

- ✓ Overcoming regulatory hurdles in Asia
  - Draw a picture of regulatory environment in Asia after 5 years -
  - ✓ Goal, Hurdle/Challenge, Approach

# ***RA-EWG's Plan in FY2017***

***Continue to promote training for further dissemination of GRM and to provide APAC RA-EWG support for better regulatory environment in Asia.***

- Continue to promote the GRM training in Asia
  - Continuous implementation of the APEC GRM CoE Workshop
    - Consider improvement of the curriculum based on the feedback from the pilot training
  - Implementation of the GRM/GSubP training in each economy
    - Expand the regions where the training is implemented
- Enhance the regulatory environment by the APAC RA-EWG activities:
  - Task A
    - Support activities and suggestions to the GRevP to promote GRM
  - Task B
    - Activities to solve regulatory problems in each region

# *Thank you very much!*



<http://apac-asia.com/>