Promotion of Good Submission Practice in Asia

April 5th, 2017
6th Asia Partnership Conference of Pharmaceutical Associations

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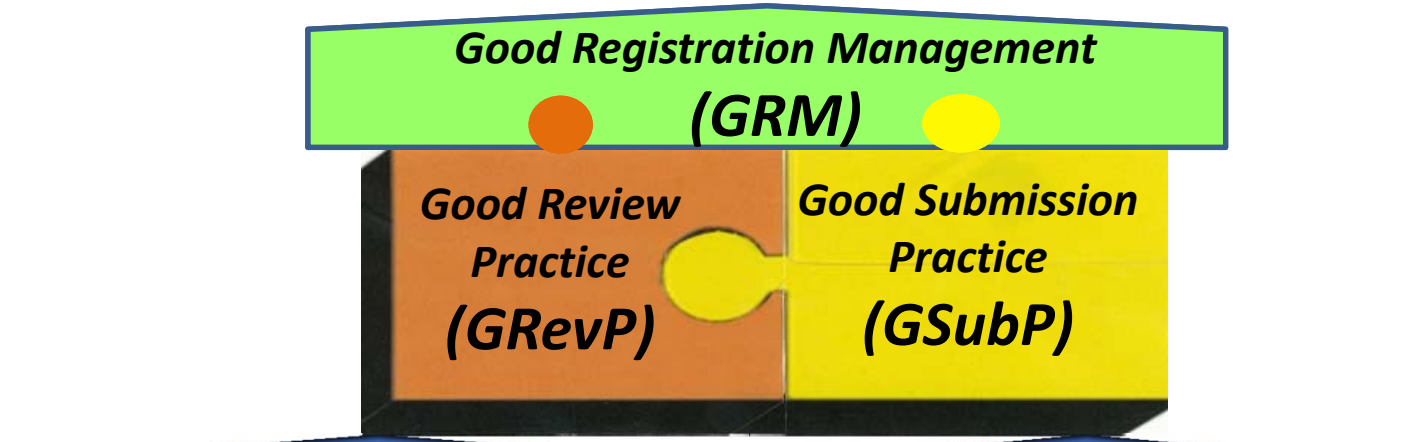
Promotion of Good Registration Management

Realize early access to new medicines for peoples in Asia

Enhance efficiency of NDA review



Make proposals to support facilitation of GRevP

Improve quality of submission and its management

APAC Position Paper

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

- *Reduced number of critical deficiencies*
- *Decrease of rejections*

APAC GSubP Guideline

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6th APAC, Apr 5th, 2017

Contents

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
- 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
- GRM CoE Pilot training program started

2016 APEC GRM Regulatory Science CoE Pilot Workshop (Nov 15th – 17th, 2016)

Day1	Day 2		Day 3	
Common Session Basic concept of GRM Overview of Good Submission /Review Effective Communication for GRM	***Reviewer Session*** Managing the review Communi-cation Fundamen-tals and case studies	***Applicant Session*** Planning of Application Prep of Application Dossier	***Reviewer Session*** Review Critical thinking Conducting the review Rolling out GRM training in each economy	***Applicant Session*** Communi-cation during review period Rolling out GRM training in each economy
			Common Session Panel Discussion on Competency	

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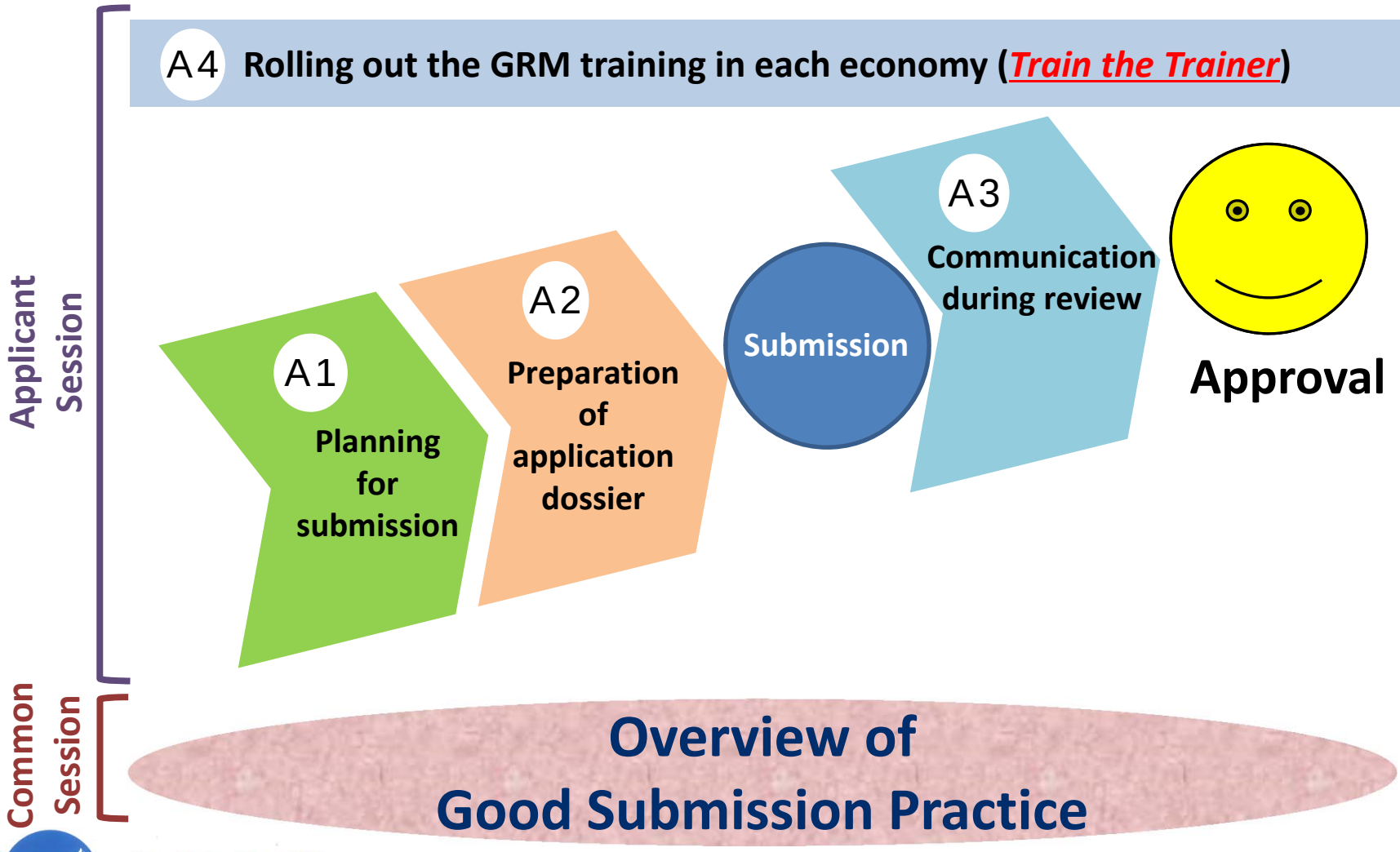
Curriculum for Good Submission Practice



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Participants for Applicants Session

Trainers/Facilitators

Trainer	Japan	JPMA	6
	Singapore	SAPI	3
		CORE	2
Facilitator	Thailand	PReMA	2
Secretariat	Japan	JPMA	1
Total			**14**

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
Total		**29**

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Phots

Applicant Session
Case Studies
Gr. Discussions
etc.

Common Session *Lectures*

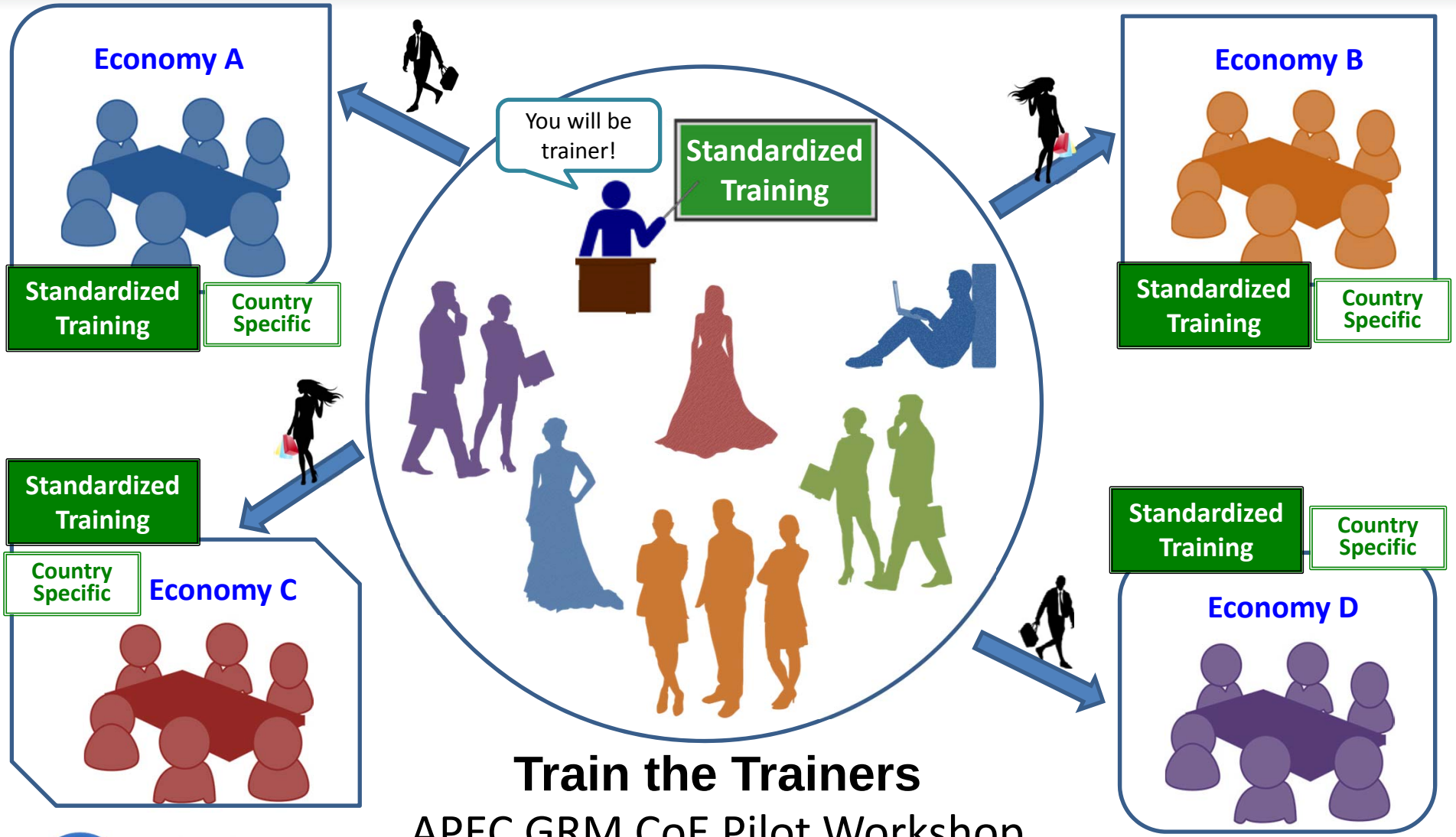
Feedback from Trainees for Applicant Session

- **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

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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

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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***

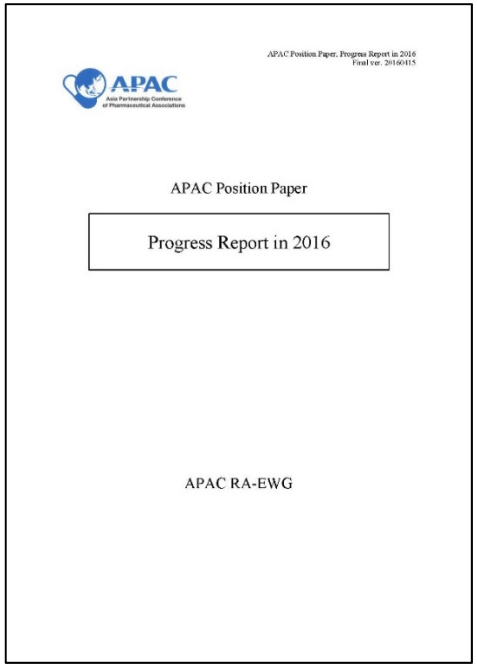
#4: Facilitating ***collaborative training program and workshop*** between the regulatory authorities and industry

#5: Facilitating ***generation of review report in English***

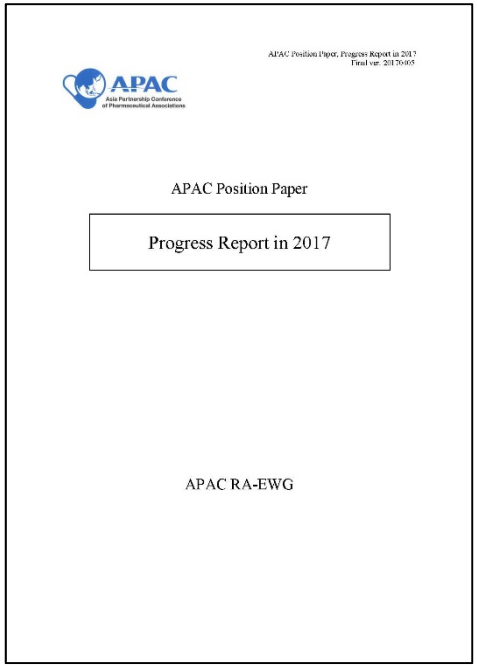
Task A Progress Report

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

5th APAC in 2016



6th 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)

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

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

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RA-EWG's Plan in FY2017

Task B

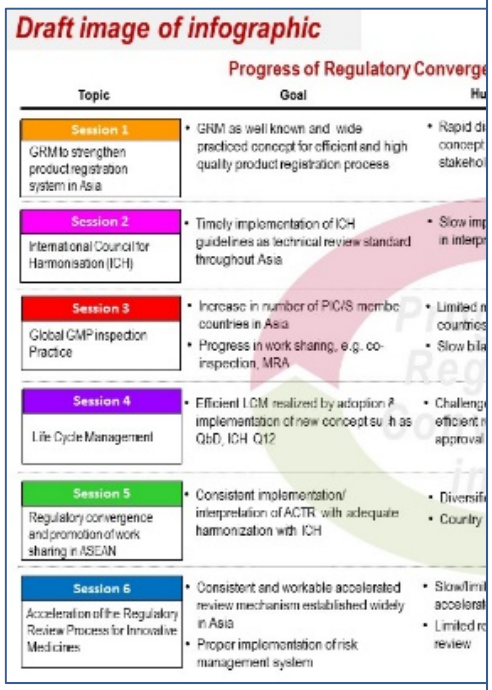
Promote regulatory convergence of NDA requirements in Asia

- 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



E.g.)

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

- *Date & Venue*
  - ✓ April 6th – 7th, 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/