6th APAC RA-EWG Session

Towards Efficient and High-Quality Registration Process for Innovative Medicines in Asia
-Campaign for Rolling out the Good Registration Management-

GRM Pilot CoE workshop: Reviewers training

Chao-Yi (Joyce) Wang
Director, Division of Medicinal Products, TFDA

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食品藥物管理署
Food and Drug Administration

http://www.fda.gov.tw/

Outline

- Promotion of Good Registration Management (GRP and GSP) in APEC
- GRM Pilot CoE workshop: Reviewers training
- Conclusion and Future Plan

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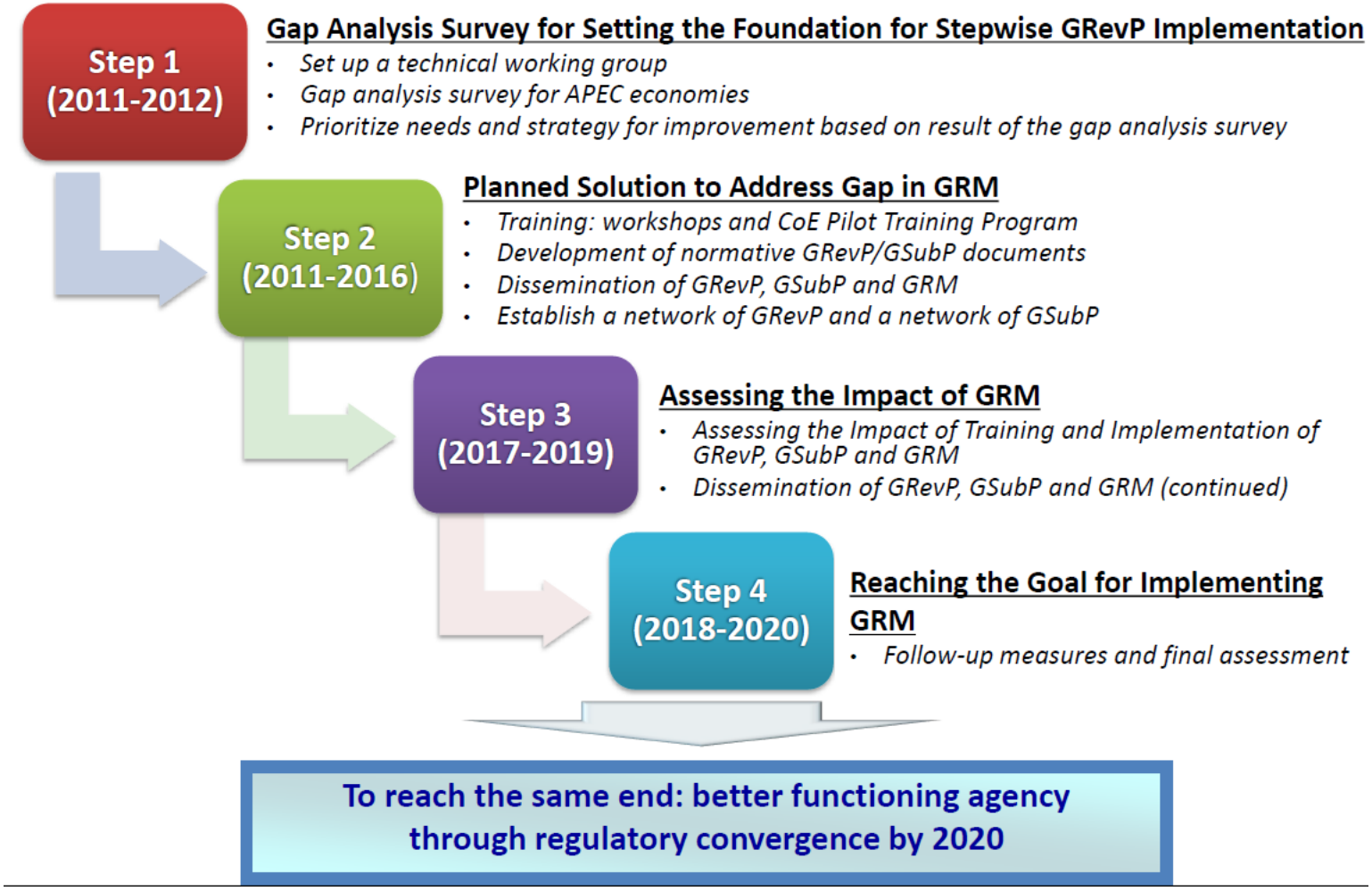
Goals of the APEC GRM roadmap and each key element

- GRM:
  - A concept to promote efficient registration process for medical products by promoting GRevP and GSubP cooperatively
- Goals of Roadmap:
  - To promote the concept of GRM
  - To enhance mutual trust for regulatory convergence among the APEC member economies by 2020

Good Review Practice (GRevP)	Good Submission Practice (GSubP)
To strengthen the **performance**, **predictability**, and **transparency** of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy.	To enhance the **quality** and **efficiency** of the medical product registration process by **improving the quality of submission** as well as its management.

Specific Activities and Timeframe of the GRM Roadmap



Milestones of the GRM Roadmap

Year	Milestone
2011	Good Review Practice (GRevP) was endorsed as a priority work area (PWA) by APEC LSIF-RHSC. Chinese Taipei was endorsed as the champion.
2013	APEC 2020 Roadmap for GRevP on Medical Products was endorsed.
2014	Good Submission Practice (GSubP) was endorsed as a PWA by RHSC.
2014-2015	**Good review practices: guidelines for national and regional regulatory authorities was adopted and published by WHO.**
2016	**Good Submission Practice Guideline for Applicants was endorsed by RHSC.** **GRevP and GSubP were merged as a PWA entitled Good Registration Management (GRM).** A combined roadmap was endorsed by RHSC. Chinese Taipei and Japan were endorsed as the co-champions. **RAPS Taiwan Chapter was endorsed as a Center of Excellence (CoE) for GRM pilot program by RHSC. A CoE Pilot Workshop was held in Taipei in Nov 2016.** Mexico Cofepris was endorsed as a CoE for GRM pilot program by RHSC.
2017	**TFDA in partnership with RAPS Taiwan Chapter was endorsed as a formal APEC GRM CoE by RHSC.**

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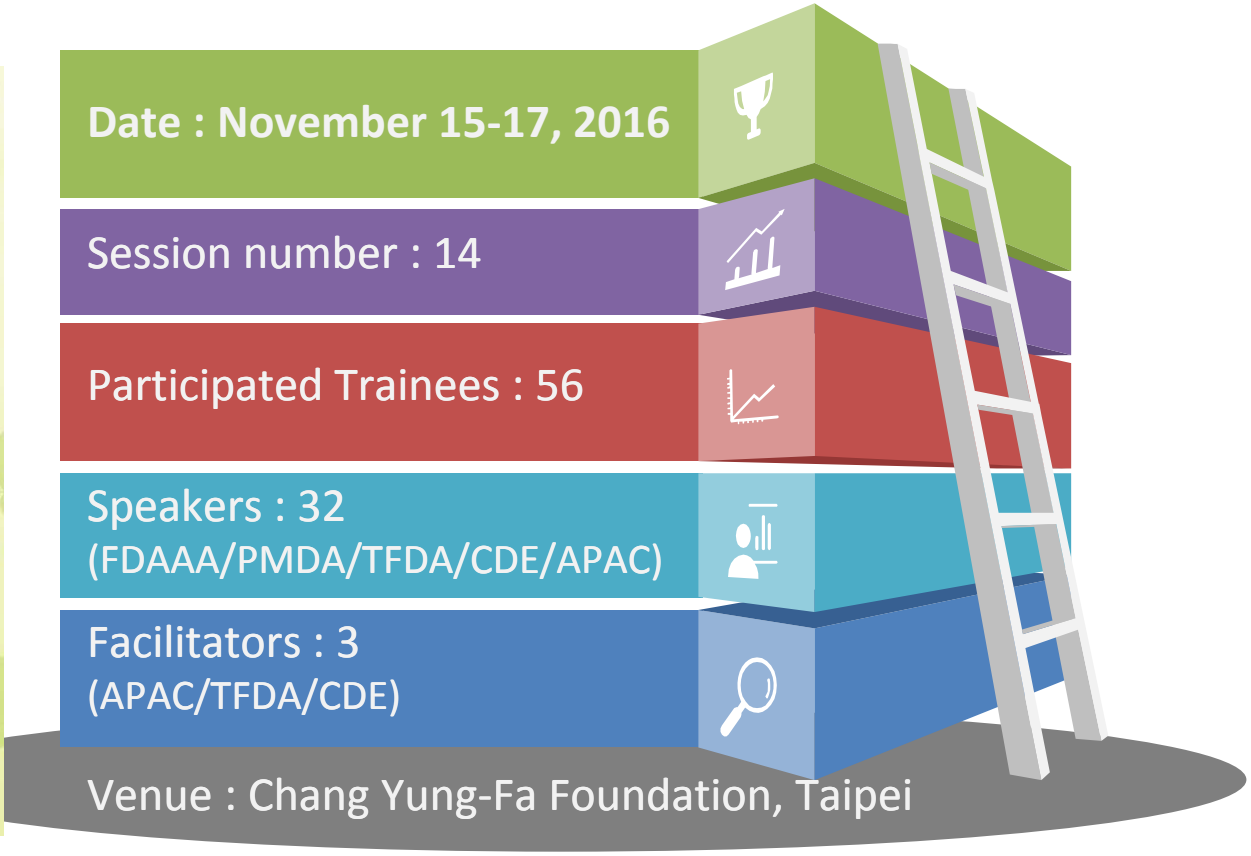
2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop



http://www.raps-in-taiwan.org.tw/apec/index.html

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Participant Analysis

Total GRM Trainees
Chile (1)
China (3)
Hong Kong (2)
Indonesia (3)
Japan (2)
Korea (2)
Malaysia (3)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Philippines (3)
Singapore (3)
Thailand (5)
Taiwan (23)
Vietnam (1)
56 APEC delegates
15 APEC member economies

Reviewer-specific sessions

Reviewers
Chile (1)
Indonesia (3)
Malaysia (1)
Mexico (2)
Papua New Guinea (2)
Peru (1)
Thailand (2)
Taiwan (14)
Vietnam (1)
27 APEC delegates
9 APEC member economies

Applicant-specific sessions

Applicants
China (3)
Hong Kong (2)
Japan (2)
Korea (2)
Malaysia (2)
Philippines (3)
Singapore (3)
Thailand (3)
Taiwan (9)
29 APEC delegates
9 APEC member economies

* Most of the trainees had more than 3 years of hands-on experiences in review or submission.

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Learning objectives and core curriculum were developed based on GRevP guidelines and GSubP guidelines

GRevP Guidelines (WHO)

Table of Contents

1. Introduction
2. Glossary
3. **Principles of a good review**
4. **Managing the review**
   - Project management
   - Quality management
   - SOPs
   - Review process stages
5. **Communications**
   - Intra-agency
   - Interagency
   - With applicants
   - With external experts
   - With the public
6. **Review personnel**
   - Reviewer expertise, competencies and training
   - Critical thinking
7. **Conducting the review**
   - Key elements in defining a review strategy
   - Applying the review strategy

Bibliography

GSubP Guidelines (APEC RHSC)

Table of Contents

1. INTRODUCTION
2. **PRINCIPLES OF A GOOD SUBMISSION**
3. **MANAGEMENT OF SUBMISSION**
   - Planning for Submission
   - Preparation and Submission of Application Dossier
   - Quality Check
4. **COMMUNICATIONS**
   - Communications with the Review Authorities
   - Communication within Applicants' Organization
5. **COMPETENCY AND TRAINING**
   - Core Competency of Applicants
   - Training and Capacity Building
6. GLOSSARY
7. REFERENCE

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Learning Objectives

Principles

- The principles of Good Review Practices (GRevP) and Good Submission Practices (GSubP)

Good Review

- What is needed for regulators to accomplish good review
  - **Conducting and managing the review**
  - **Good communication with applicants**
  - **Competency for regulators**

Good Submission

- What is needed for applicants to accomplish good application
  - **Planning and preparation of application dossier**
  - **Good communication with regulators**
  - **Competency for applicants**

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Core Curriculum

GRM
Good Registration Management

Common Sessions

- Basic concept of GRM
- An Overview of Good Review
- An Overview of Good Submission
- Case Study: Effective Communication for GRM

GRevP
Good Review Practices

Reviewers-Specific Sessions

- Managing the review
- Communication : Fundamentals and Case Studies
- Review personnel - Critical thinking
- Conducting the review
- Rolling out the GRM training program in each economy
- Panel Discussion (competencies)

GSubP
Good Submission Practices

Applicants-Specific Sessions

- Planning of Application
- Preparation of application dossier / Practice : How to prepare application dossier
- Effective communications Focusing follow-up actions during review period
- Rolling out the GRM training program in each economy
- Panel Discussion (competencies)

Group photo for all workshop participants

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Workshop photos

Case studies

Lectures

Group discussion

Reviewers Training (1)

Day 1 Common Sessions

- **Basic Concept of GRM**
  - APEC Roadmap to Promote GRM; overview of GRM curriculum
- **An Overview of Good Review**
  - principles of a good review; overview of GRevP guidelines; challenges
- **An Overview of Good Submission**
  - principles of a good submission; overview of GSubP guidelines
- **Case study: Effective Communication for GRM**
  - Effective communications between applicants and regulatory authorities throughout product life cycle - practices in PMDA


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Reviewers Training (2)

Day 2 Reviewer-Specific Sessions

- **Managing the review**
  - An introductory overview of managing the review
  - Experience sharing: how US FDA, PMDA and TFDA/CDE manage the review
  - Group discussions to understand the current practices, challenges and gaps in managing reviews among different APEC member economies
- **Communication: Fundamentals and case studies**
  - An overview of good communications for a regulatory authority
  - Practices in PMDA
  - An interactive session with case studies




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Reviewers Training (3)

Day 3 Reviewer-Specific Sessions and Combined Panel Discussion

- **Review Personnel – Critical Thinking**
  - How to apply critical thinking in conducting reviews and making decisions
- **Conducting the Review**
  - Points to be considered for a good review
- **Rolling out the GRM training program in each economy**
  - How to develop local GRevP training by following trainer's manual
- **Panel discussion on regulatory professionals' competencies**
  - RAPS' Regulatory Competency Framework; identify competency gaps

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Feedback from Onsite Survey
(Reviewers)

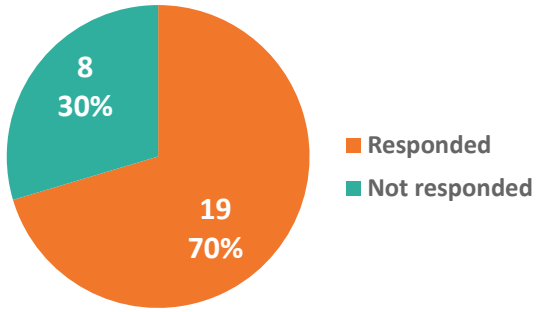
Topics/presentations of the 2016 pilot workshop most useful to trainees

Reviewers
Critical thinking, Communication
Rolling out the GRM training program in each economy
Case studies
Group discussion
All topics
Conducting the review
Managing the Review

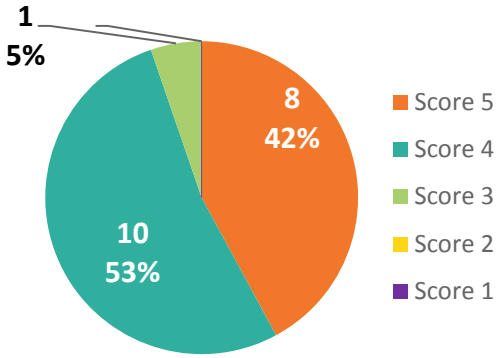
Topics/areas trainees would like to see in the future GRM workshop

Reviewers
Critical thinking in risk/benefit considerations, different product areas, review disciplines and post-approval modifications
Communication
Interactive sessions between reviewers and applicants
Others: effective tools and approaches used for GRevPs, key aspects to perform a review

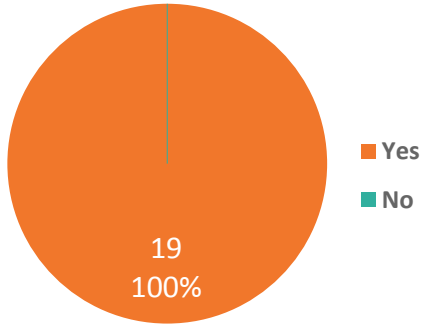
Follow-up survey 2 months after the pilot (Reviewers)



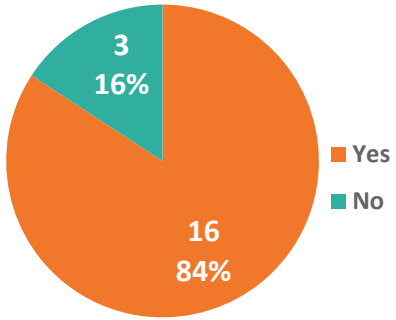
(1) Response rate 19/27 (70%)



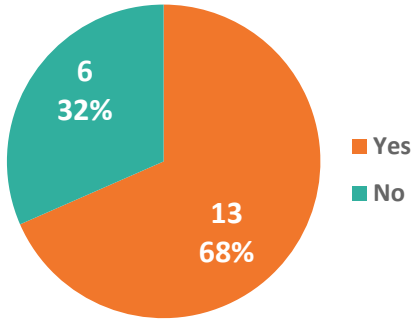
(2) Very helpful in improving review practices 18/19 (95%)



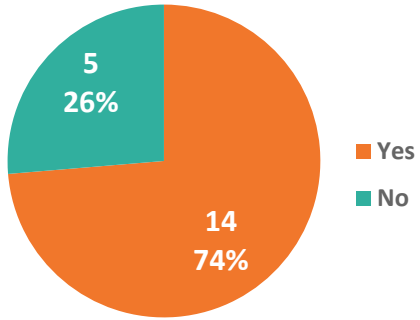
(3) Will recommend colleagues to participate in the workshop 19/19 (100%)



(4) Take action to promote GRM 16/19 (84%)



(5) Plan to conduct local training 13/19 (68%)



(6) Will use the training manuals to organize training 14/19 (74%)

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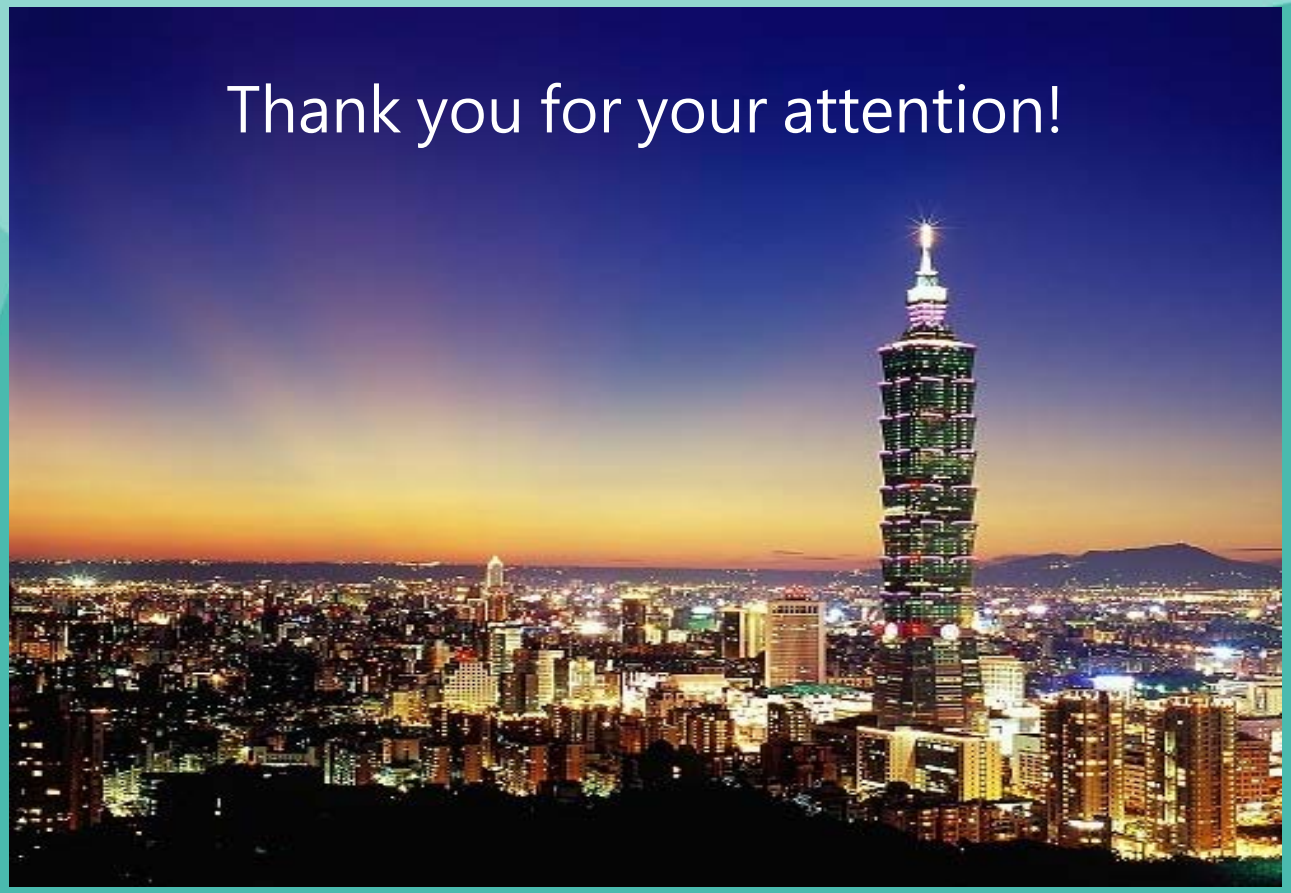
Challenges from Organizers' Perspectives

- Provide a curriculum which meets the need of all individual trainees with variability in background.
  - For Reviewer-Specific Sessions, participants are from different APEC member economies with **different levels of regulatory sophistication** and with **focus in different review disciplines**.
  - For Applicant-Specific Sessions, case studies were provided based on the experiences of **well-resourced companies** which focus on registration of new drugs.
- Provide more opportunities for regulators and applicants to efficiently interact with each other.

Conclusion and Future Plan

- It was a successful CoE pilot with
  - good partnership and collaboration,
  - significant interactive elements, such as interactive discussions, group discussions, case studies, and practices,
  - good rating and overall satisfaction, and
  - endorsed as a formal APEC CoE by APEC RHSC

- For the next workshop in October 2017, we plan to
  - create more collaborative sessions to allow trainees from industry to talk to regulators,
  - provide more case studies and interactive discussions, and
  - put more emphasis on the topics of "communication" and "critical thinking".



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