2017 APEC RHSC Regulatory Science Center of Excellence (CoE) for Good Registration Management (GRM) - Pilot Workshop

The Outcomes of 2016 APEC GRM CoE Pilot Workshop – Experience Sharing from TFDA

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Mexico City

衛生福利部
食品藥物管理署
FDA Food and Drug Administration

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RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

Outline

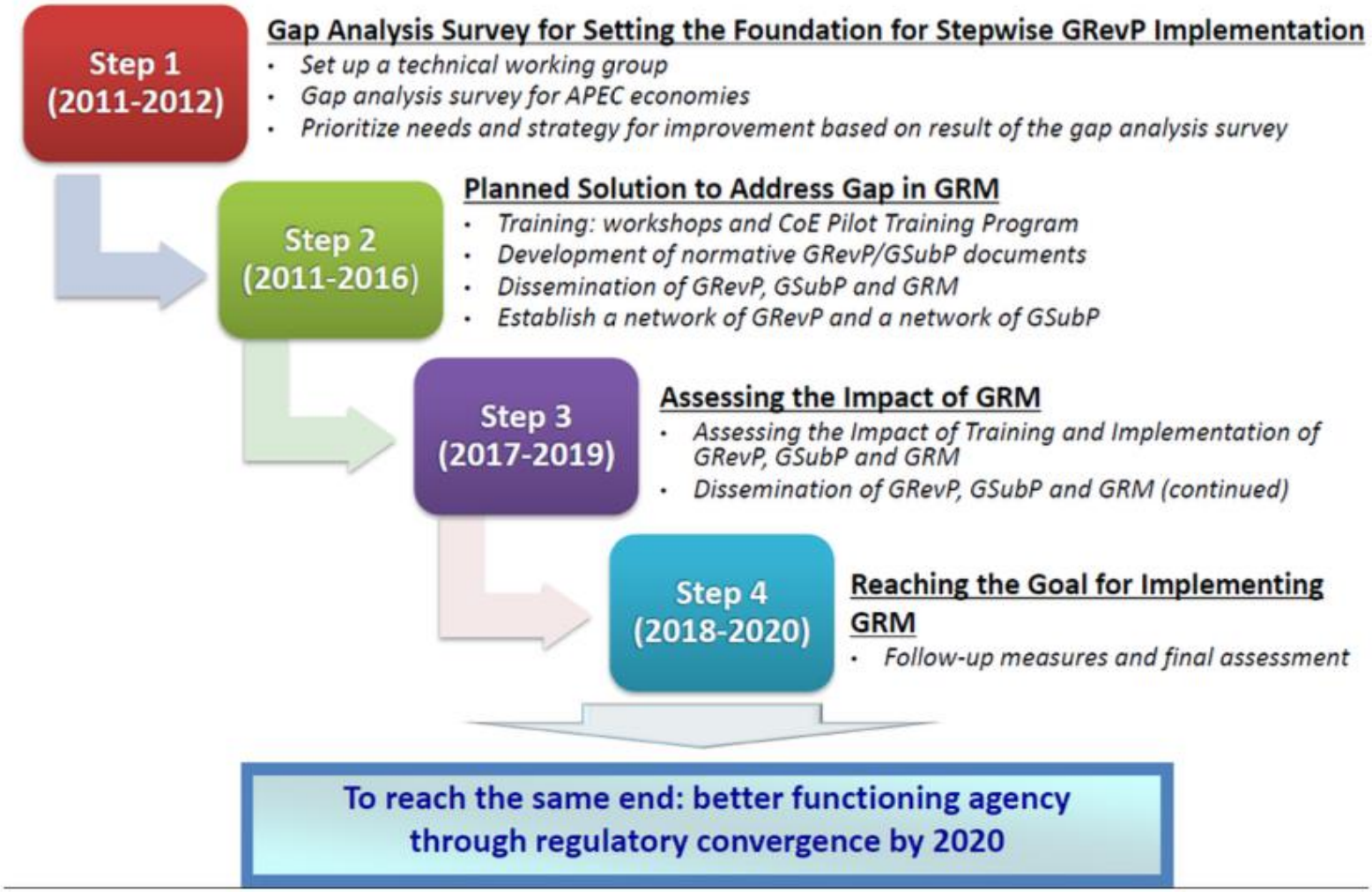
- Promotion of Good registration Management (GRevP and GSubP) in APEC
- 2016 APEC GRM CoE Pilot Workshop
- Conclusion and Future Plan

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 GSupP 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 Time frame 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.**

2016 APEC GRM CoE Pilot Workshop

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2016 APEC GRM CoE Pilot Workshop

Workshop co-organizers

Regulatory Harmonization Steering Committee

APEC LSIF Regulatory Harmonization Steering Committee

Life Sciences Innovation Forum

Food and Drug Administration, Ministry of Health and Welfare, Taiwan (Chinese Taipei)

Pharmaceuticals and Medical Devices Agency, Japan

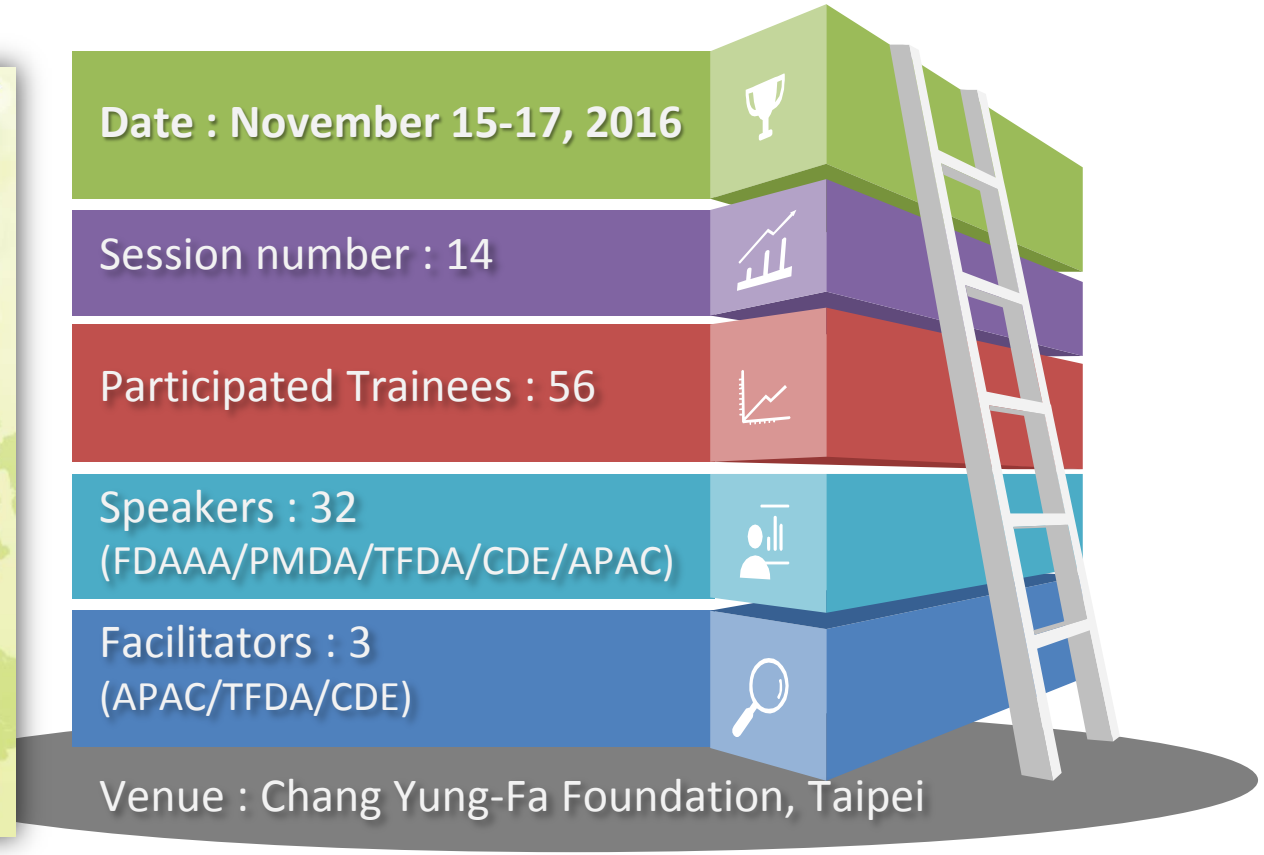
Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

Asia Partnership Conference of Pharmaceutical Associations

APEC Harmonization Center

Regulatory Affairs Professionals Society (RAPS)
RAPS Taiwan Chapter

2016 APEC GRM Regulatory Science Center of Excellence Pilot Workshop



Participant analysis (1)

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

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

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

Participant analysis (2)

Question: How many years have you worked on the management of regulatory review or regulatory submission?

Reviewers	Responders (total 27)
about 3 years or less	11 (41%)
3 to 5 years	8 (30%)
5 to 10 years	3 (11%)
more than 10 years	5 (18%)

- 26 were from regulatory authorities and 1 was from academia.

Applicants	Responders (total 29)
about 3 years or less	3 (10%)
3 to 5 years	1 (4%)
5 to 10 years	5 (17%)
more than 10 years	20 (69%)

- 28 were from industry and 1 was from academia

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 regulators to accomplish good application

- Planning and preparation of application dossiers
- Good communication with regulators
- Competency for applicants

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

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

Program of 2016 GRM Pilot Workshop

Day 1	Day 2		Day 3	
Common Sessions	***Reviewer Sessions***	***Applicant Sessions***	***Reviewer Sessions***	***Applicant Sessions***
Basic Concept of GRM	Managing the review	Planning of application	Review personnel – Critical thinking	Communication during review period
Overview of Good Review/ Submission	Communication: Fundamentals & Case studies	Prep of application dossiers	Conducting the review	
Effective Communication of GRM			Rolling out the GRM in each economy	Rolling out the GRM in each economy
			Common Session	
			Panel discussion on competency	

Group photo of all GRM participants

Workshop photos

Case studies

Lectures

Group discussion

Onsite Survey: Effectiveness Analysis

General Satisfaction with the Workshop

General Satisfaction	Response Average	Responders (response rate)
Were level and amount of pre-training materials adequate?	4.33	42 (75%)
Did the workshop enhanced your understanding of GRM concept?	4.49	42 (75%)
Were your expectations for this workshop met?	4.33	42 (75%)
Overall satisfaction	4.48	42 (75%)

Scale 1 = Poor and 5 = Excellent

Average rating score is above 4. The pilot is considered with good satisfaction.

Onsite Survey: Curriculum Analysis (1)

Rating for Common Sessions

Common Sessions	Session 1 Basic concept of GRM		Session 2 An Overview of Good Review		Session 3 An Overview of Good Submission		Session 4 Case Study: Effective Communication for GRM	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	3.96	33 (59%)	4.03	33 (59%)	4.18	33 (59%)	4.21	33(59%)
The adequacy of the time allocation for this session	4.27	33 (59%)	4.30	33 (59%)	4.24	33 (59%)	4.27	33(59%)
Facilitation and presentation of the content	4.12	33 (59%)	4.21	33 (59%)	4.27	33 (59%)	4.24	33(59%)
Total evaluation	4.15	33 (59%)	4.24	28 (50%)	4.34	32 (57%)	4.27	33(59%)

Onsite Survey: Curriculum Analysis (2)

Rating for Reviewer-Specific Sessions

Reviewers-Specific Sessions	Session R1 Managing the review - an Overview		Session R2 Communication : Fundamentals and Case Studies		Session R3 Review personnel - Critical thinking		Session R4 Conducting the review		Session R5 Rolling out the GRM training program in each economy	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	4.36	22 (76%)	4.45	22 (76%)	4.60	23 (79%)	4.47	23 (79%)	4.47	23 (79%)
The adequacy of the time allocation for this session	4.40	22 (76%)	4.54	22 (76%)	4.60	23 (79%)	4.52	23 (79%)	4.52	23 (79%)
Facilitation and presentation of the content	4.40	22 (76%)	4.59	22 (76%)	4.69	23 (79%)	4.52	23 (79%)	4.52	23 (79%)
Total evaluation	4.40	22 (76%)	4.59	22 (76%)	4.69	23 (79%)	4.60	23 (79%)	4.52	23 (79%)

Onsite Survey: Curriculum Analysis (3)

Rating for Applicant-Specific Sessions

Applicants-Specific Sessions	Session A1 Planning of Application		Session A2 Preparation of application dossier / Practice : How to prepare application dossier		Session A3 Effective communications Focusing follow-up actions during review period		Session A4 Rolling out the GRM training program in each economy	
	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)	Response Average	Responder (response rate)
The adequacy of training materials	4.36	22 (76%)	4.36	22 (76%)	4.7	20 (69%)	4.44	18 (62%)
The adequacy of the time allocation for this session	4.40	22 (76%)	4.36	22 (76%)	4.45	20 (69%)	4.42	19 (65%)
Facilitation and presentation of the content	4.5	22 (76%)	4.27	22 (76%)	4.5	20 (69%)	4.47	19 (65%)
Total evaluation	4.47	21 (72%)	4.47	22 (76%)	4.55	20 (69%)	4.47	19 (65%)

Onsite Survey: Curriculum Analysis (3)

Rating for Panel Discussion on Regulatory Professionals' Competencies

Session A5/R6 Panel discussion	Response Average	Responder (response rate)
The adequacy of training materials	4.26	37 (66%)
The adequacy of the time allocation for this session	4.17	39 (69%)
Facilitation and presentation of the content	4.25	39 (69%)
Total evaluation	4.22	39 (69%)

Feedback from Onsite Survey (1)

Feedback from 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

Feedback from Onsite Survey (2)

Feedback from Applicants

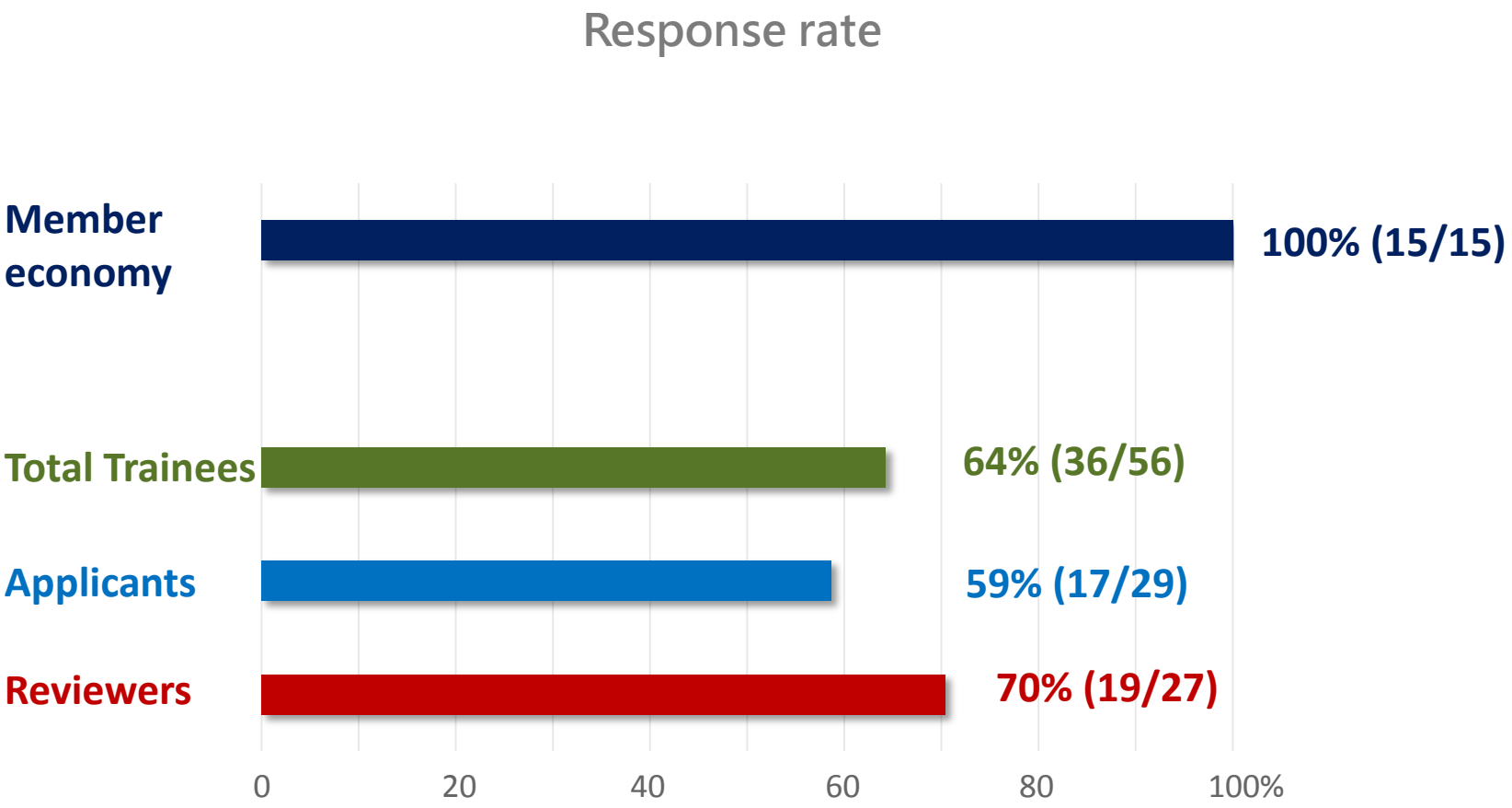
Topics/presentations of the 2016 pilot workshop most useful to trainees

Applicants
Communication
Planning for submission
QC & Dossier Preparation
Case study & group discussion are very good.
All topics
The tools, the exercises.
Section A3. Effective communications - Focusing follow-up actions during review period / Practice: Case study of how to handle inquires

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

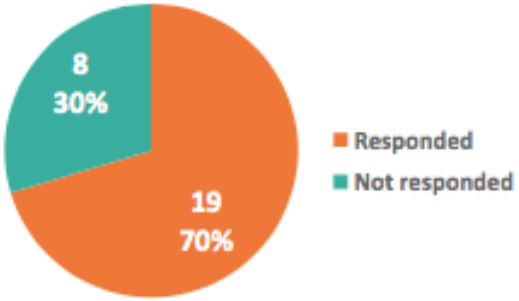
Applicants
Effective communication
More case studies: implementation of GRM, submission to regulatory authorities among Asia/US/EU
Interactive sessions between reviewers and applicants
Others: tools for improving quality of submissions, project management, risk management, critical thinking

Follow-up survey 2 months after the pilot (1)

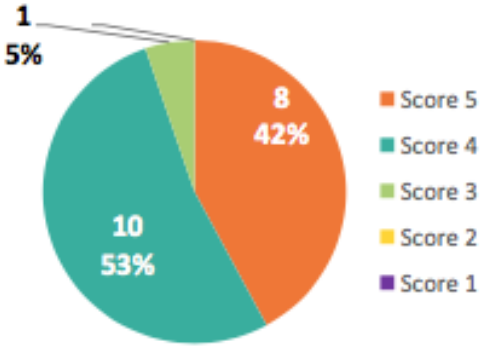


Follow-up survey 2 months after the pilot (2)

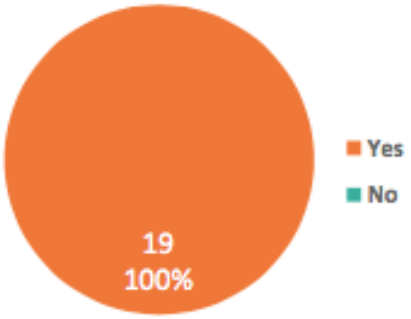
Reviewers



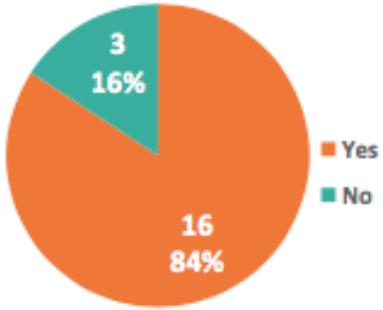
(1) Response rate 19/27 (70%)



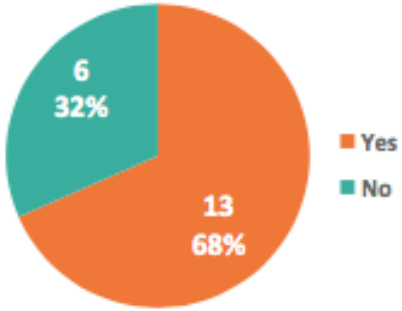
(2) Very helpful in improving review practices 18/19 (95%)



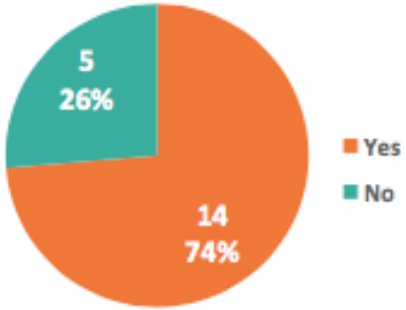
(3) Will recommend colleagues to participate in the workshop 19/19 (100%)



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



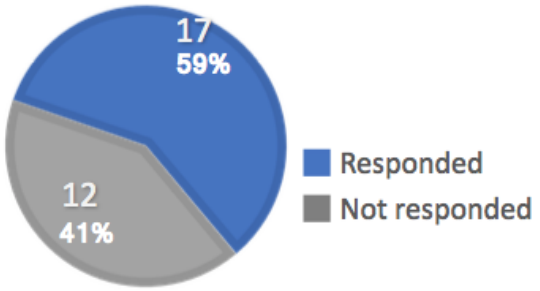
(5) Plan to conduct local training 13/19 (68%)



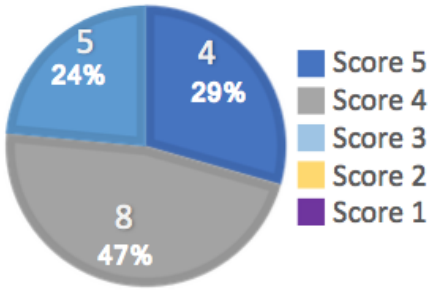
(6) Will use the training manuals to organize training 14/19 (74%)

Follow-up survey 2 months after the pilot (3)

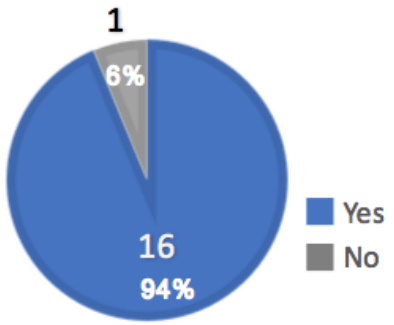
Applicants



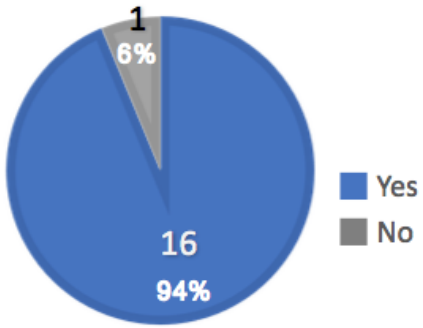
(1) Response rate 17/29 (59%)



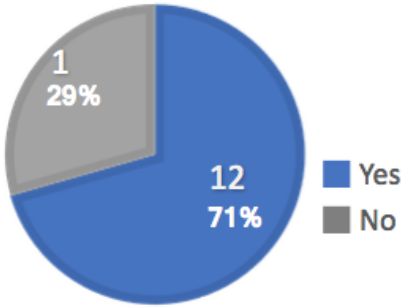
(2) Very helpful in improving submission practices 12/17 (71%)



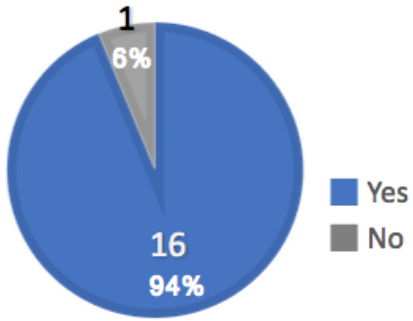
(2) Will recommend colleagues to participate in the workshop 16/17 (94%)



(4) Take action to promote GRM 16/17 (94%)



(5) Plan to conduct local training 12/17 (71%)



(6) Will use the training manuals to organize training 16/17 (94%)

Conclusion and Future Plan

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Conclusion and Discussion

- 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
  - Endorsement as a formal CoE by APEC RHSC under the partnership of TFDA and RAPS Taiwan Chapter
- For the future training program, 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”.

Challenges from Organizer's 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.

Upcoming Event

Program of 2017 GRM Pilot Workshop

<table>
<tr><th colspan="2">Day 1</th><th colspan="2">Day 2</th><th>Day 3</th></tr>
<tr><td colspan="2">Common Session
Keynote speech: Basic Concept of GRM

Overview of Good Review/ Submission

Experience sharing from different APEC member economies</td><td rowspan="2">Reviewer Session

Review personnel – Critical thinking

Communication: Fundamentals & Case studies</td><td rowspan="2">Applicant Session

Prep of application dossiers

Communication during review period</td><td rowspan="2">Common Session

Communication
-Practices and interactive discussions between reviewers and applicants

Panel discussion on competency

Rolling out the GRM in each economy</td></tr>
<tr><td>Reviewer Session

Managing & Conducting the review</td><td>Applicant Session

Planning of application

Special Considerations and Case Studies for Management of Submission for Generic Drug Applications</td></tr>
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Thank you for your attention.

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