7th APAC RA Session

Regulatory landscape for "Access to Innovative Medicine" in Asia
- Further dissemination of GRM

Outcomes of 2017 APEC GRM CoE Workshop

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Outline

- Promotion of Good Registration Management (GRP and GSP) in APEC
- Outcomes of 2017 APEC GRM CoE Workshop
- Conclusion and Future Plan

Goal of the GRM roadmap

- **Purpose:** To promote GRevP and GSubP cooperatively
- **Long-term goals:**
  - Promote the concept of GRM
  - Enhance mutual trust for regulatory convergence among APEC member economies by 2020

Good Review Practices (GRevP)	Good Submission Practice (GSubP)
To help **achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality** in the content and management of reviews	To **enhance the quality and efficiency of the medical product registration process** by improving the quality and management of submission

Specific Activities and Timeframe

Step 1 | **Step 2** | **Step 3** | **Step 4**

Step 1 : 2011-2012

Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation

Step 2: 2011-2016

- Planned solutions to address gaps
- GRM CoE Pilot

Step 3: 2017-2019

- Assessing impact of GRM using Performance indicators

Step 4: 2018-2020

Reaching the Goal for Implementing GRM

2011 APEC GRevP Workshop (basic)

2016 APEC GRM CoE Pilot

2012 APEC GRevP Workshop (advanced)

2017 APEC GRM CoE

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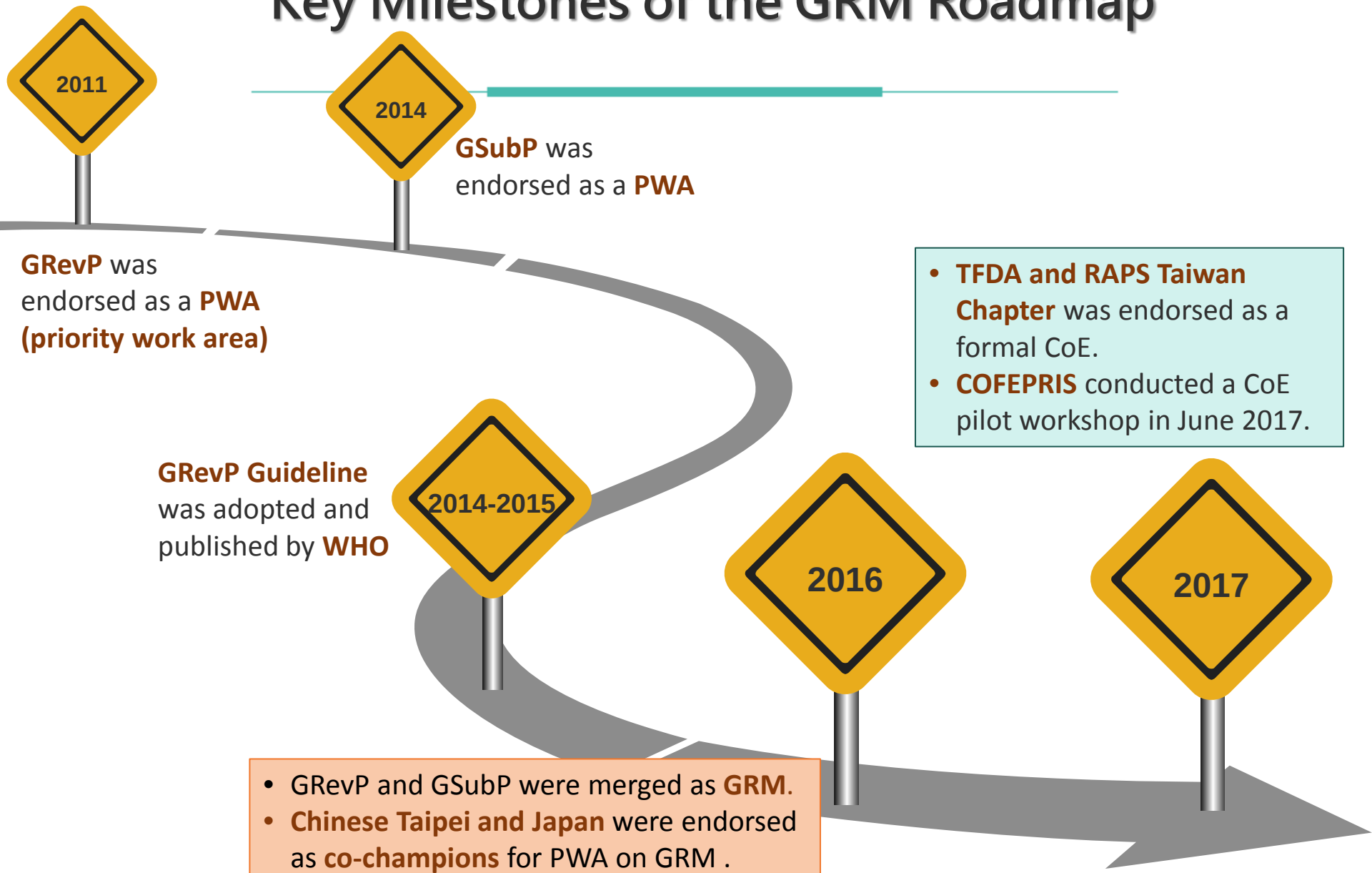
Key Milestones of the GRM Roadmap



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2017 APEC GRM Regulatory Science Center of Excellence Workshop

Date: Oct 30 - Nov 2, 2017
Venue: NTUH International Convention Center, Taipei

2 Keynote Speeches /13 Sessions

Participating Trainees : 70

Speakers : 35 (TFDA/CDE/PMDA/HC/MHRA/ Philippines FDA/APAC/MOPI/CKF/Duke-NUS CoRE)

Facilitators : 3 (APAC)

Regulatory Harmonization Steering Committee APEC Life Sciences Innovation Forum

APAC

Pmda

FDA

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY Driving Regulatory Excellence™

CKF

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Learning Objectives

To learn the followings for implementation of GRM

- The principles of GRevP and GSubP
- What is needed for **regulators** to accomplish good review
  - Conducting and managing the review
  - Good communication with applicants
  - Competency for regulators
- What is needed for **applicants** to accomplish good application
  - Planning and preparation of application dossier
  - 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
- Effective Communication for GRM
- Competency & training
- Rolling out the GRM training program in each economy

GRevP
Good Review Practices

Reviewers-Specific Sessions

- Managing the review - an Overview
- Communication : Fundamentals and Case Studies
- Review personnel - Critical thinking
- Conducting the review

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

Group Photo of All GRM Participants

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Workshop Photos

Lectures

Case studies

Group discussion

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Participant Analysis

Economies	Reviewers	Applicants	Total
Chinese Taipei	15	23	38
Hong Kong	0	1	1
Indonesia	4	4	8
Malaysia	1	4	5
Papua New Guinea	1	0	1
Philippines	3	1	4
Singapore	1	1	2
South Korea	0	2	2
Thailand	4	4	8
Vietnam	1	0	1
TOTAL	**30**	**40**	**70**

Program of 2017 GRM CoE 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

Competencies and training for reviewers and applicants

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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Common Sessions (1)

Target audience: Reviewers & Applicants

1) Basic Concept of GRM
2) An Overview of Good Review and Good Submission
   - Key principles of good reviews and good submissions
   - High level guidance on the processes

Good review practice (GRevP)

1. Introduction
2. Glossary
3. Principles of a good review
4. Managing the review
5. Communications
6. Review personnel
7. Conducting the review

Good Submission Practice (GSubP)

1. Introduction
2. Principle of a good submission
3. Management of submission
4. Communications
5. Competency and training
6. Glossary
7. References

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Common Sessions (2)

Target audience: Reviewers & Applicants

3) **The Role of Good Review Practices in Building Quality Review Process – Canadian Experience**

4) **Experience Sharing from Different APEC Member Economies**

- Updates from regulatory authorities of Indonesia, Malaysia, Philippines and Singapore and industry associations of Singapore and Thailand
- Current status and challenges of GRM in advanced and developing economies
- Regulatory authorities provide in-house training and the implementation of GRM is evolving.
- Industry supports local training. But sustainability is an issue.

Common Sessions (3)

Target audience: Reviewers & Applicants

5) **Communications:**
   - Introductory lectures
   - Group discussions among reviewers and applicants

6) **Competencies and Training for Reviewers and Applicants**
   - Regulatory competency framework
   - Competency gaps
   - Incorporating formal training framework for regulatory professionals

7) **Rolling Out the GRM Training Program in Each Economy**
   - Trainer's Manual
   - Facilitating Team-based Learning

Reviewer-Specific Sessions

Target audience: Reviewers

- Managing and Conducting the Review
  - Experiences sharing from invited experts:
    - Review of new drug applications
    - Review generic drug applications
  - Experiences sharing from trainees:
    - Current review processes in 8 participating economies

- Critical thinking
  - Case studies and group discussions on scientific reviews of new drug applications
  - Common deficiencies and case studies on scientific reviews of generic drug applications

- Communications - Fundamentals and Case Studies for Regulatory Authorities
  - Experience sharing from regulatory authorities of Taiwan, Canada and Philippines

Applicant-Specific Sessions

Target audience: Applicants

- Planning of Application
  - What do we want? - What do we need? - How do we do it?
- Preparation of Application Dossier/ Practice: How to Prepare Application Dossier

- Effective Communications - Focusing Follow-up Actions During Review Period /Practice: Case Study of How to Handle Inquires
  - Communication throughout development
  - With health authority & Among applicants
- Good Submissions for Generic Drug Applications
  - Good Submission Practice in Malaysia & ASEAN
  - Good Submissions For Generic Drug Applications

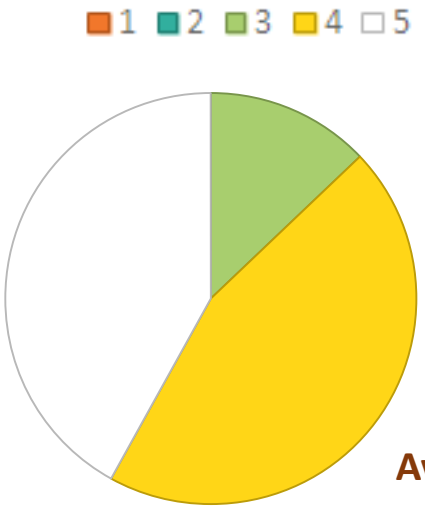
General Satisfaction

Scale 1=poor and 5 =excellent
Average score is around 4, could be considered as good satisfaction

Were level and amount of pre-training materials adequate? **Average: 3.94**

Did the workshop enhanced your understanding of GRM concept? **Average: 4.35**

Were your expectations for this workshop met? **Average: 4.19**

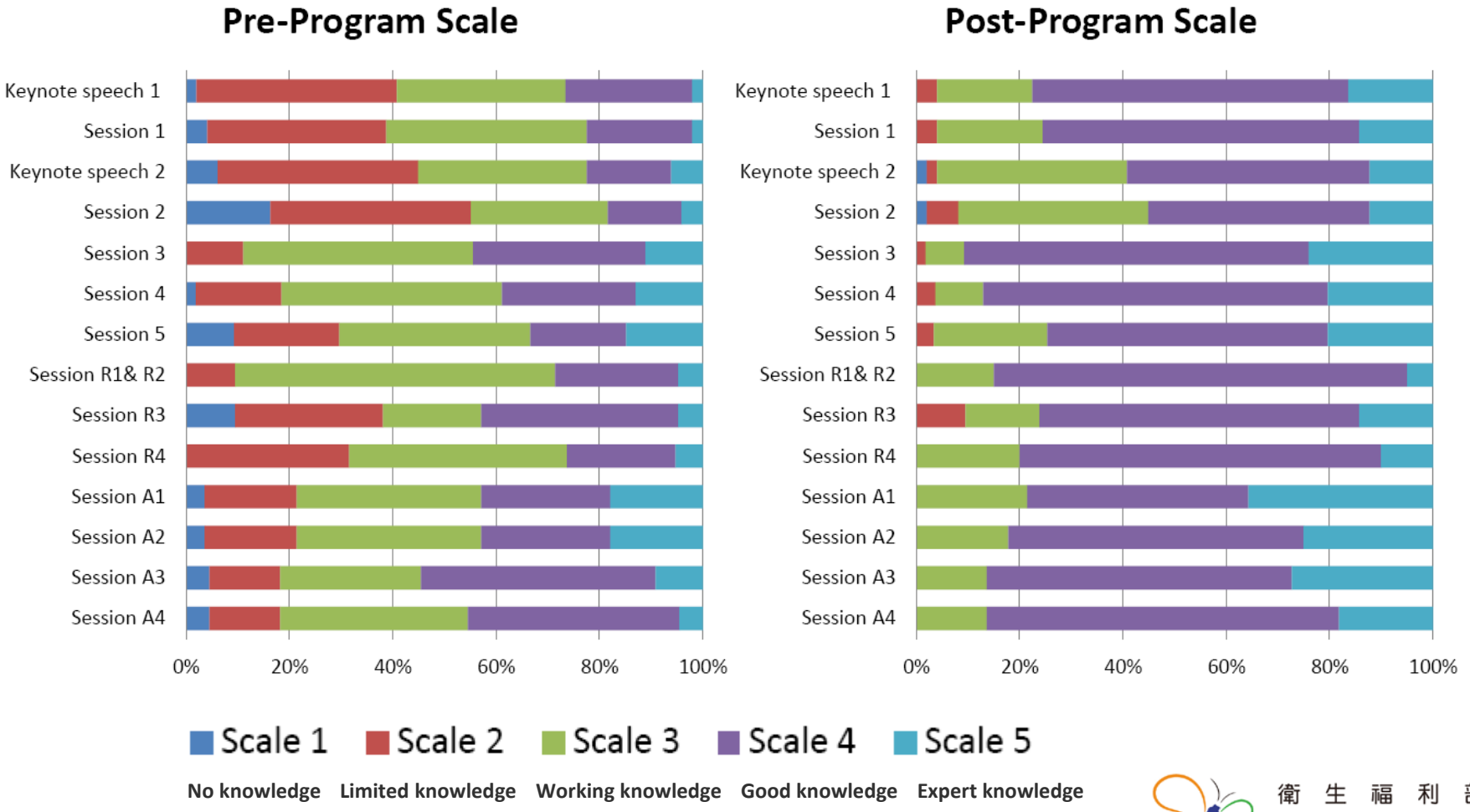


Average: 4.29

Overall satisfaction

Analysis of Knowledge Level Survey

The knowledge level scales generally increased after the sessions



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Summary of the Feedback for 2017 Workshop

- Basically, most sessions have good satisfactions.
- Suggestions for workshop organizers are summarized as follows:
  - Include **regional examples of GRM implementations** and discuss on the **challenge**
  - More training in **communications** and **critical thinking**
  - Provide more **case studies** and **interactive discussions**
  - Not only use the case of drugs, but also include **other medical products**
  - Give enough time for delegates to prepare their experience sharing

Plans for the Year 2018

- Prepare to host the 2018 GRM CoE Workshop in Taipei on September 26-28, 2018
- Prepare to collaborate in organizing GRM CoE Pilot Workshops and local training with interested APEC member economies




Thank You for Your Attention




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