8th APAC RA Session: Good Registration Management

Overview of Good Registration Management (GRM)

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Goal of the GRM roadmap

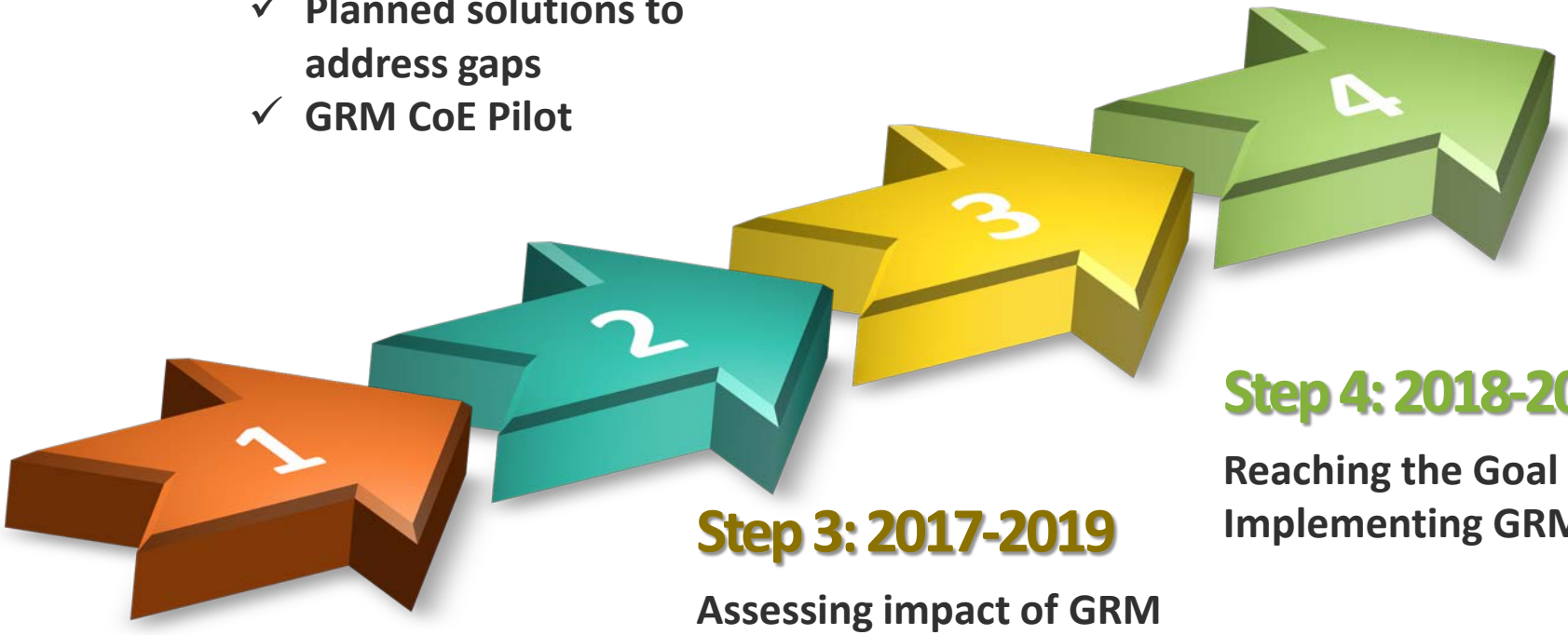
- **Purpose:**
  To promote GRevP and GSubP cooperatively
- **Long-term goals:**
  - Promote the concept of GRM
  - Enhance mutual trust for regulatory convergence among APEC member economies by 2020

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 2: 2012-2016

- ✓ Planned solutions to address gaps
- ✓ GRM CoE Pilot



Step 1 : 2011-2012

- ✓ Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation

Step 3: 2017-2019

Assessing impact of GRM

- *Assessing the impact of training and implementation of GRevP, GSubP and GRM*
- *Dissemination of GRevP, GSubP and GRM*

Step 4: 2018-2020

Reaching the Goal for Implementing GRM

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APEC GRM CoE and Pilot CoE

institution	Workshop	Topic	
		GRevP	GSubP
CoE: TFDA/RAPS Taiwan Chapter	2016 pilot (Nov 2016, Taipei) ; 15 economies, 56 members 2017 workshop (Oct 2017, Taipei) ; 10 economies, 70 members 2018 workshop (Sep 2018, Taipei) ; 14 economies, 62 members **2019 workshop (Sep 2019, Taipei)**	✓	✓
Pilot CoE: Cofepris	2017 pilot (Jun 2017, Mexico City)	✓	✓
Pilot CoE: Thai FDA	**2019 pilot (Nov 2019, Bangkok)**	✓	✓

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Photos @2018 GRM Workshop TFDA/RAPS Taiwan

Certification

Case studies

Lectures

Group Discussion

Lectures

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GRM Local Training Activities

Name of institution	Activities	Topic	
		GRevP	GSubP
TFDA/RAPS Taiwan Chapter	2017 training (Nov 2017) 2018 training (Nov 2018) **2019 training (2019)**	✓	✓
IRPMA Taiwan	2018 training (Mar 2018) 2018 training (Aug 2018) **2019 training (2019)**	✓	✓
Singapore	2017 training (Apr 2017)		✓
Thailand	2018 training (Jun 2018)	✓	✓
Malaysia	2018 training (July 2018)		✓
The Philippines	**2019 training (Mar 2019)**	✓	✓

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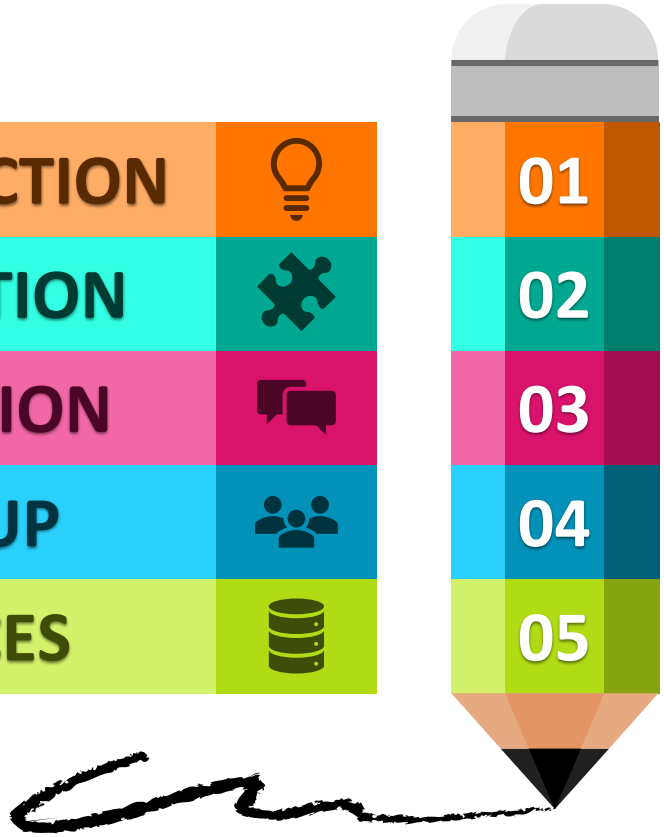
Photos @2018 GRM Local Training IRPMA Taiwan

GSubP Related Training Program
- ✓ Dossier preparation
- ✓ Common Technical Document
- ✓ RTF criteria

GRevP Related Training Program
- ✓ Communication
- ✓ Common Deficiency on CMC, PT, PK/PD, Clinical and Statistics

GRM Trainer's Manual ver. 2018

Organizing the GRM Training Workshop



INTRODUCTION	To help certified GRM Trainers to organize an effective training program in their economy.
PREPARATION	To establish a training team, curriculum, agenda, materials and pre-learning files.
CONDUCTION	To carry out the workshop following the developed agenda.
FOLLOW-UP	To utilize the self-evaluation, follow-up survey to assess effectiveness of the training.
REFERENCES	Good Review Practice Guideline, WHO Good Submission Practice Guideline, APEC

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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 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
- 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

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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)	Good Submission Practice (GSubP)
1. Introduction	1. Introduction
2. Glossary	2. Principle of a good submission
3. Principles of a good review	3. Management of submission
4. Managing the review	4. Communications
5. Communications	5. Competency and training
6. Review personnel	6. Glossary
7. Conducting the review	7. References

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Common Sessions (2)

Target audience: Reviewers & Applicants

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

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

5) **Rolling Out the GRM Training Program in Each Economy**
   - Trainer's Manual
   - Facilitating team-based learning

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Reviewer-Specific Sessions

Target audience: Reviewers

1) **Managing and Conducting the Review**
   - Experiences sharing from experts:
     - Review of **new drug applications** or **generic drug applications**
   - Experiences sharing from trainees:
     - Current review processes

2) **Critical thinking**
   - Case studies and group discussions on scientific reviews
   - Common deficiencies and case studies

3) **Communications - Fundamentals and Case Studies**
   - Experience sharing from regulatory authorities or industries

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Applicant-Specific Sessions

Target audience: Applicants

1) **Planning of Application**
   - What do we want? - What do we need? - How do we do it?

2) **Preparation of Application Dossier/ Practice:** How to Prepare Application Dossier

3) **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

2019 GRM CoE Workshop in September

Organizers:

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

FDA

Pmda

APAC Asia Partnership Conference of Pharmaceutical Associations

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Thank You for Your Attention




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PANEL DISCUSSION

1. **Why did your economy hold GRM?**
   - ✓ What did you expect for GRM at the beginning?

2. **What was improved by GRM implementation?**
   - ✓ Communication between Agency and industry
   - ✓ Dossier preparation: quality, speed etc.
   - ✓ Predictability of assessment process

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