Goal of the GRM Roadmap

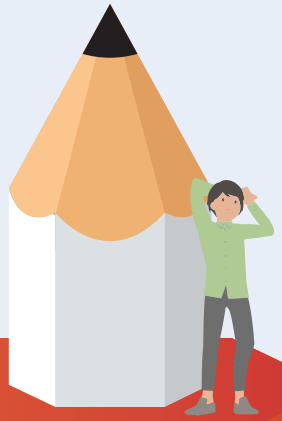
Good Registration Management

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



Review Authorities

Applicants

Good Review Practices (GRevP)

GRevP

To help **achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality** in the content and management of reviews

Good Submission Practice (GSubP)

GSubP

To **enhance the quality and efficiency of the medical product registration process** by improving the quality and management of submission

Specific Activities and Timeframes

Step 4
2020~

Reaching the Goal for Implementing GRM

Step 3
2017–2019

Assessing impact of GRM
– Dissemination of GRM (continued)
– Assessing the impact of training and implementation of GRM using KPIs

Step 2
2011–2016

Planned solutions to address Gap in GRM

Step 1
2011–2012

Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation

APEC GRM CoE Training Activities

Taipei

2019 APEC GRM CoE Workshop in Taipei

—**September 17-19, 2019** (TFDA/RAPS Taiwan Chapter)

1

APEC TRAINING

August 2019-February 2020

2019 APEC GRM Pilot CoE Workshop in Bangkok

—**October 26-28, 2019** (Thai FDA)

Bangkok (Pilot)

GRM Local Training Activities

2 LOCAL TRAINING

Chinese Taipei
- GRevP + GSubP — 2017 training (Nov 2017)
- GSubP — 2018 training (Mar/Aug 2018)
- GRevP + GSubP — 2018 training (Nov 2018)
- GRevP + GSubP — 2019 training (June/July 2019)

Thailand
- GRevP + GSubP — 2018 training (June 2018)

Malaysia
- GSubP — 2018 training (July 2018)
- GRevP + GSubP — 2019 training (October 2019)

Singapore
- GSubP — 2017 training (Apr 2017)

Indonesia
- GRevP + GSubP — 2019 training (August 2019)

KPI Assessment of GRM Implementation is on-going
The result will be shared with all in the 10th APAC

Topics
Activities
Economy