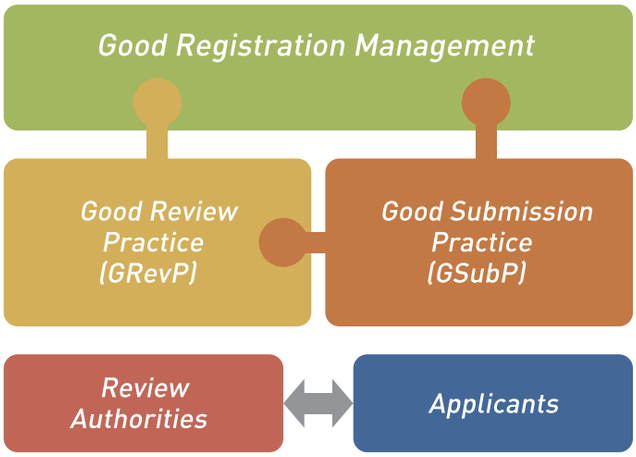
Goal of the GRM Roadmap



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)

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

Good Submission Practice (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

2011-2012	2011-2016	2017-2019	2020~
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation	Planned solutions to address Gap in GRM	Assessing impact of GRM ✓ Dissemination of GRM (continued) ✓ Assessing the impact of training and implementation of GRM using KPIs	Reaching the Goal for Implementing GRM

APEC GRM CoE Training Activities

August 2019-February 2020

APEC TRAINING

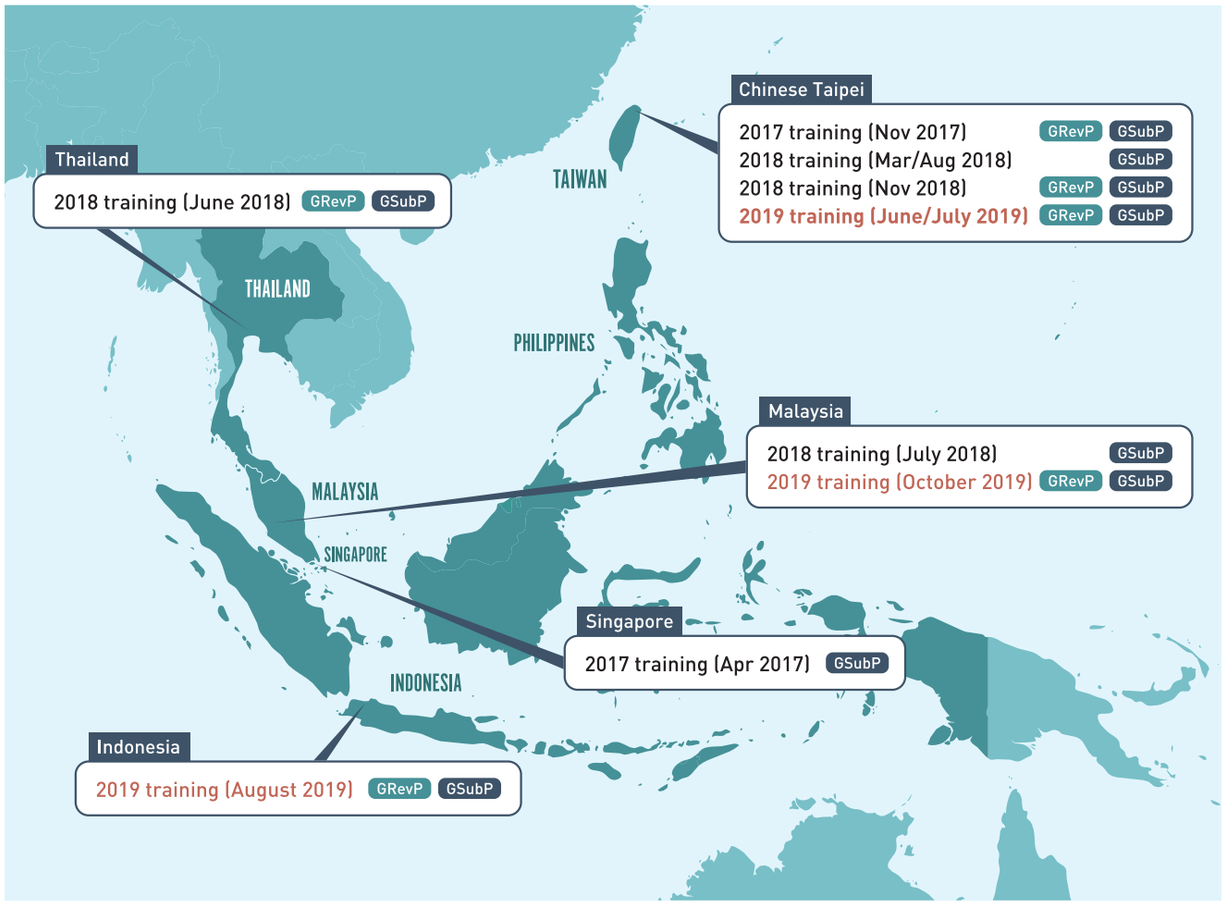
2019 APEC GRM CoE Workshop in Taipei

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

2019 APEC GRM Pilot CoE Workshop in Bangkok

— October 26-28,2019 (Thai FDA)

GRM Local Training Activities



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