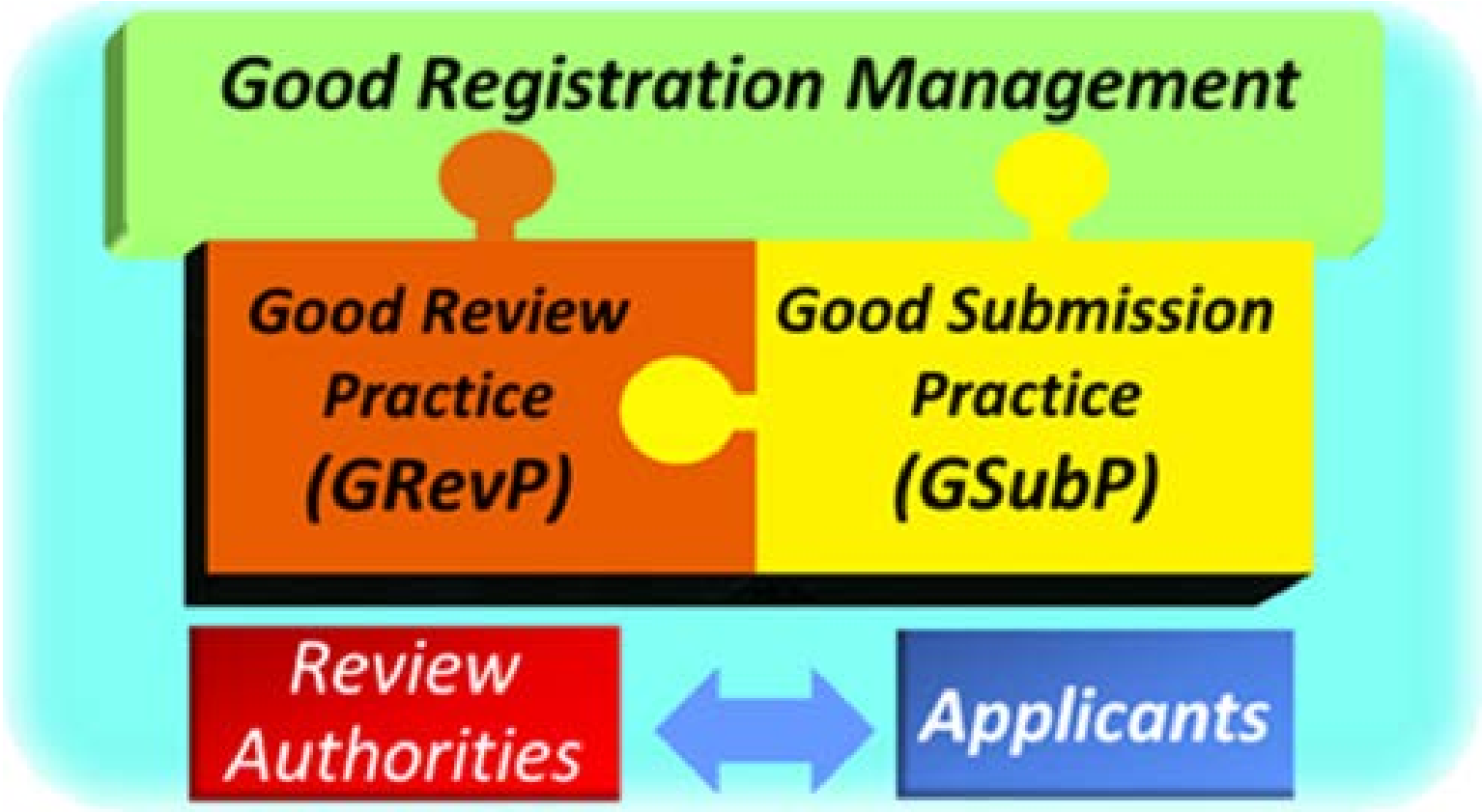
Wrap Up



Concept of GRM is to promote efficient registration process for medical products by promoting GRevP and GSubP cooperatively.

We learned that;

- GRM Workshops in each economy
- Train-the trainer model
- Cooperation between industries and regulatory authorities

- powerful tools
- successful for promoting GRM so far,

…….but there are still room to improve

Sharing know-how through workshops

Understanding of concept of GRM
& Implementation of GRM

Go for win-win situation!

Consensus of RA session

Good Registration Management

～ Success of “Train the Trainers” ～

- Continue to support “Good Registration Management (GRM)” led by Taiwan FDA and PMDA under Asia-Pacific Economic Cooperation (APEC) for aiming improvement of quality of regulatory submission and review on innovative medicines in Asia

  1) Co-host the APEC GRM Workshop, which has started since 2016, with Taiwan FDA and PMDA, and continuously developing trainers who can promote GRM in their own countries in Asia (“**Train the Trainers**”)

  2) Further enhancing the quality of regulatory submission and review of innovative medicine by actively supporting GRM Workshops in Asia, such as APEC GRM Pilot Workshop newly hosted by Thailand, based on “**Train the Trainers**”