Regulations and Approvals Session

Introduction of RA-EWG Session

April 5, 2017 APAC RA-EWG Osamu Inagaki



Goal and Approach of APAC RA-EWG

APAC Mission:

To Expedite the Launch of Innovative Medicines

for the Peoples in Asia

Good Registration Management

- ✓ Introduce Good Submission Practice
- ✓ Support promotion of Good Review Practice

Convergence of NDA Requirements

✓ Make proposals to facilitate regulatory convergence of NDA requirements

Review

Promote each task in close collaboration vith the Asian regulatory authorities.

GRM Roadmap for stepwise implementation



Obtained endorsement of APEC RHSC Feb 24, 2016

Step 1 (2011-2012)

Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation

- Set up a technical working group
- Gap analysis survey for APEC economies
- · Prioritize needs and strategy for improvement based on result of the gap analysis survey

Step 2 (2011-2016)

Planned Solution to Address Gap in GRM

- Training: workshops and CoE Pilot Training Program
- Development of normative GRevP/GSubP documents
- Dissemination of GRevP, GSubP and GRM
- Establish a network of GRevP and a network of GSubP

Assessing the Impact of GRM

 Assessing the Impact of Training and Implementation of GRevP, GSubP and GRM

of GRevP, GSubP and GRM (continued)

- Training: workshops and CoE Pilot Training Program
- Development of normative GrevP/GSubP document
- Dissemination of GRevP, GSubP and GRM

eaching the Goal for Implementing GRM
Follow-up measures and final assessment

To reach the same end: better functioning agency

through regulatory convergence by 2020



6th APAC RA-EWG Session

Session Theme:

Towards Efficient and High-Quality Registration Process for Innovative Medicines in Asia - Campaign for Rolling out the Good Registration Management-

[Presentations]

1. GRM Pilot CoE workshop –Reviewers Training Joyce Wang (TFDA)

2. Promotion of Good Submission Practice in Asia Hatakeyama (JPMA)

[Panel Discussion]

<Key-note lecture> Forward-looking approaches & its Experiences

of PMDA's Asia Training Center Sato (PMDA)

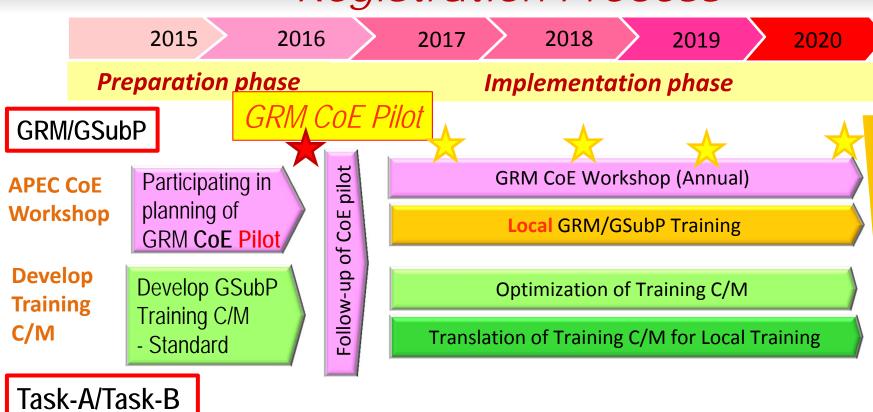
<Discussion> Challenges on the Capacity building for

quality improvement in new drug registration processes

Session closing



Towards Efficient and High-Quality Registration Process



ISK / W TUSK B

Proposal to support facilitation of GRevP

Convergence of NDA Requirements

In close collaboration with the Asian regulatory authorities.



CoE: Center of Excellence, C/M: Training Curriculum & Materials

NDA: New Drug Application

5



