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

Promote each task in close collaboration with the Asian regulatory authorities.
GRM Roadmap for stepwise implementation

Obtained endorsement of APEC RHSC
Feb 24, 2016

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

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

To reach the same end: better functioning agency through regulatory convergence by 2020

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


Preparation phase Implementation phase

GRM/GSubP GRM CoE Pilot
APEC CoE Workshop
Participating in planning of GRM CoE Pilot
Develop Training C/M
Develop GSubP Training C/M - Standard
Follow-up of CoE pilot

GRM CoE Workshop (Annual)
Local GRM/GSubP Training
Optimization of Training C/M
Translation of Training C/M for Local Training

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
Thank you!