

Session 5: Experiences Sharing from Other APEC Economies - Applicant

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APAC

Asia Partnership Conference of Pharmaceutical Associations

<http://apac-asia.com/>



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ABOUT US

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2018-05-31

[The 7th APAC Meeting: Post-](#)

WHAT WE BELIEVE



[Our Mission](#)

APAC is an industry-driven initiative led by R&D-based pharmaceutical associations from Asian economies, aiming to fulfill its mission.

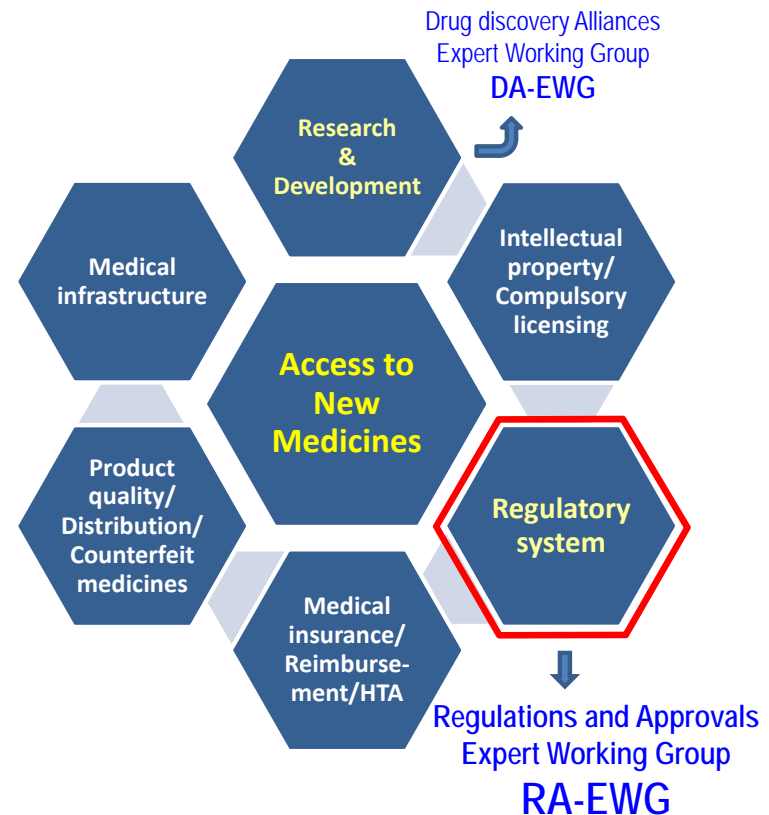
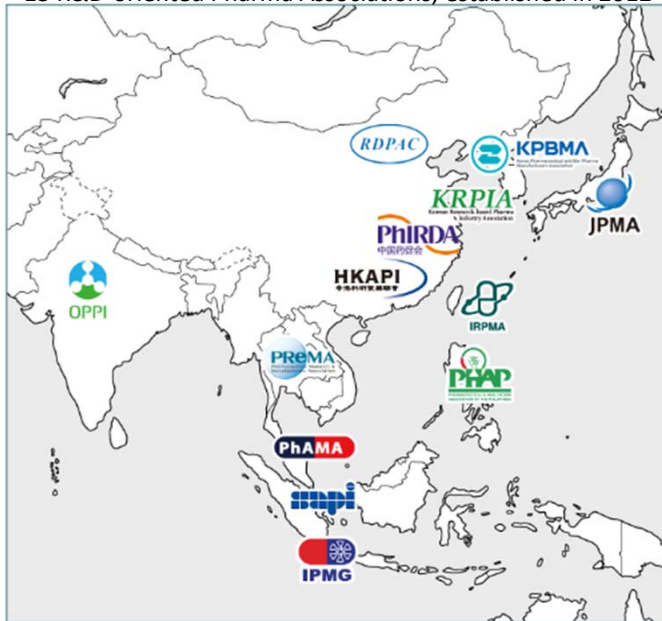
What is APAC?

APAC =Asia Partnership Conference of Pharma Associations

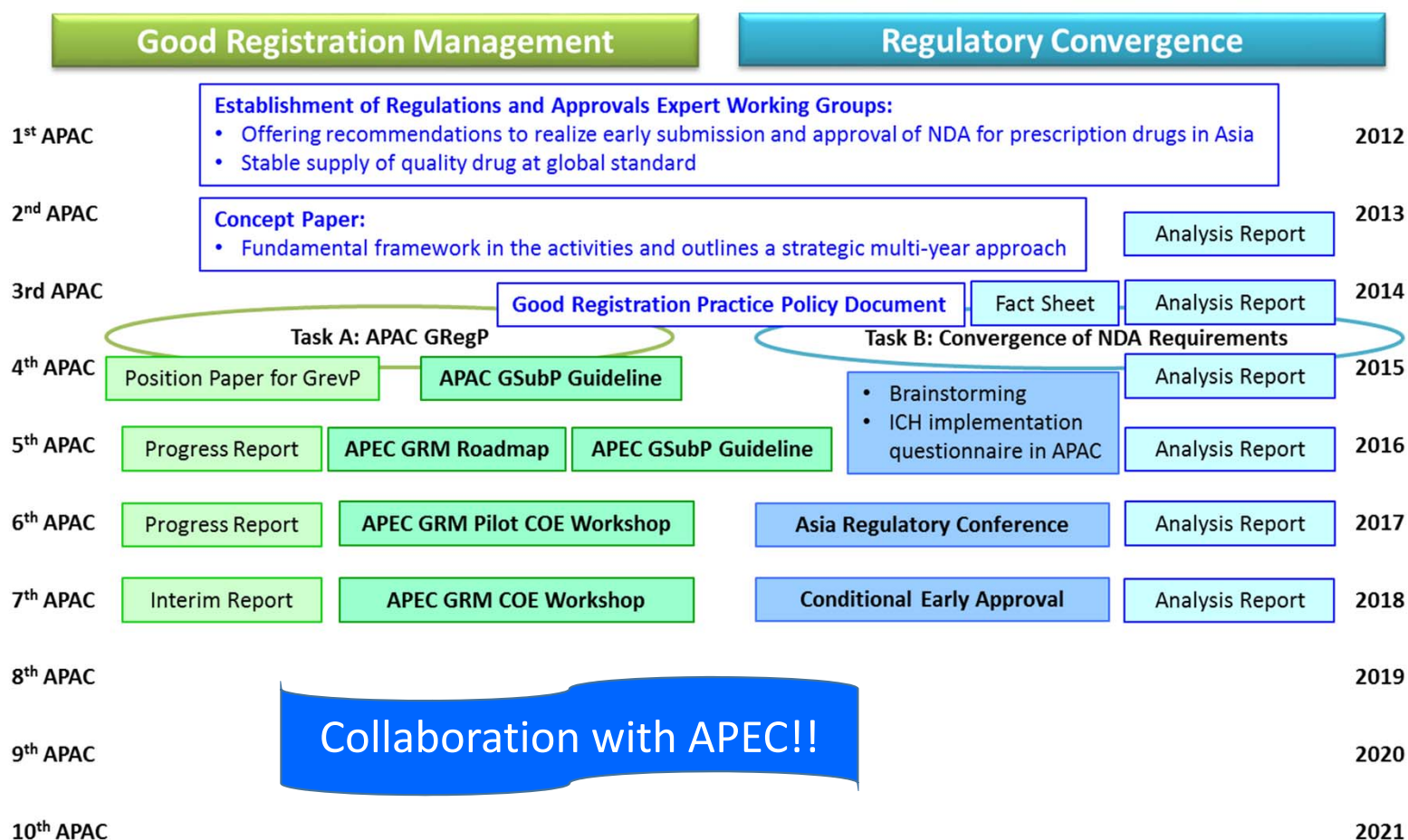
Mission:

To Expedite the Launch of Innovative Medicines for the Peoples in Asia

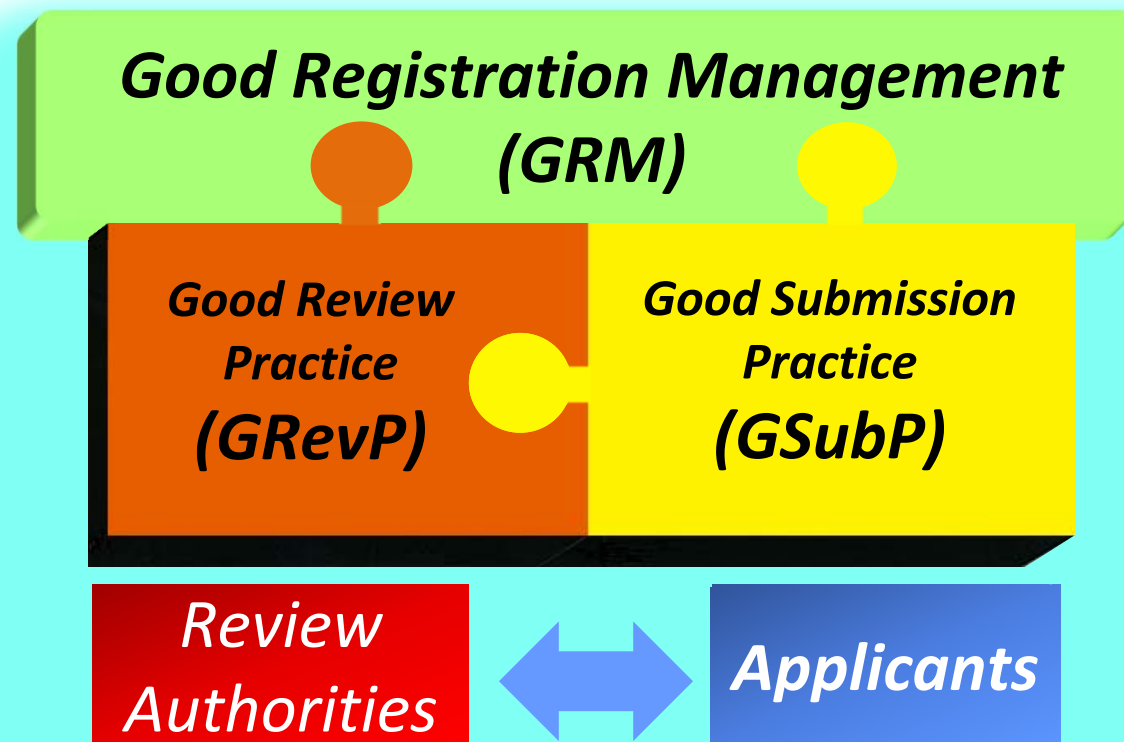
13 R&D-oriented Pharma Associations, established in 2012



History of APAC RA-EWG



Mutual Success for Review Authorities and Applicants



Early access to new medicines!!

GOOD SUBMISSION PRACTICE (GSubP) GUIDELINE FOR APPLICANTS

1 INTRODUCTION

- 1.1 Objective and scope
- 1.2 Background
- 1.3 Definition

2 PRINCIPLES OF GOOD SUBMISSION

3 MANAGEMENT OF SUBMISSION

- 3.1 Planning for Submission
- 3.2 Preparation and Submission of Application Dossier
 - 3.2.1 Writing study reports and summaries
 - 3.2.2 Compilation and assembling of dossier
 - 3.2.3 Submission of application
 - 3.2.4 Standard operating procedure for submission preparation

3.3 Quality Check

4 COMMUNICATIONS

- 4.1 Communications with the Review Authorities
 - 4.1.1 Communications in pre-submission stage
 - 4.1.2 Communications in post-submission stage
- 4.2 Communication within Applicants

5 COMPETENCY AND TRAINING

- 5.1 Core Competency of Applicants
- 5.2 Training and Capacity Building

6 GLOSSARY

7 REFERENCES

Point to Consider for training

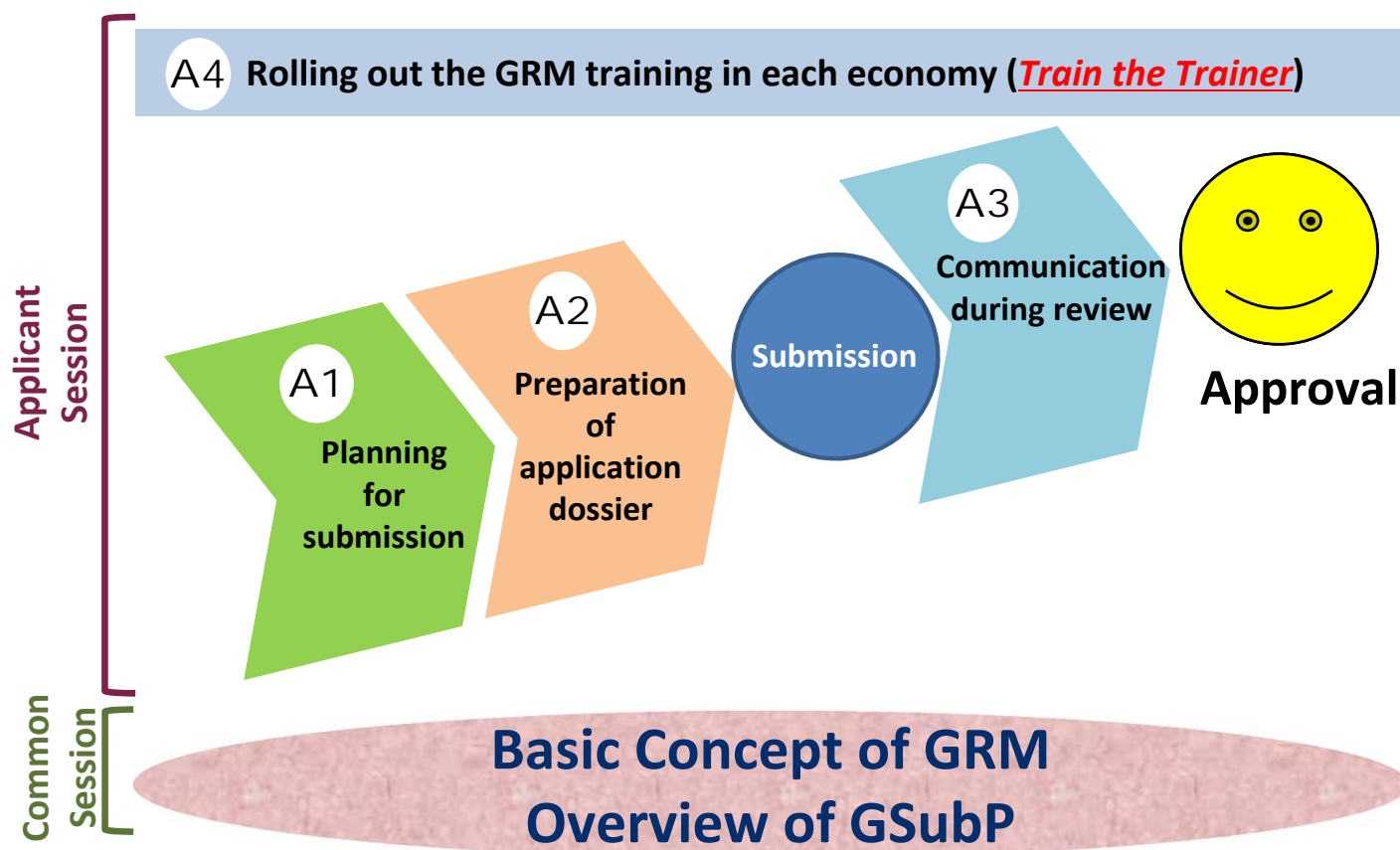
Style

- Less Lecture
- More Interactive Sessions
 - Ice Break
 - Case Study
 - Group Work
 - Group Discussion
 - Group Presentation

Content

- Universal
- Comprehensive
- Essence of submission
- Including Opportunity of Interaction among Reviewers and Applicants

Curriculum for Good Submission Practice



Photos

**Applicant
Session**
*Case Studies
Gr. Discussions
etc.*

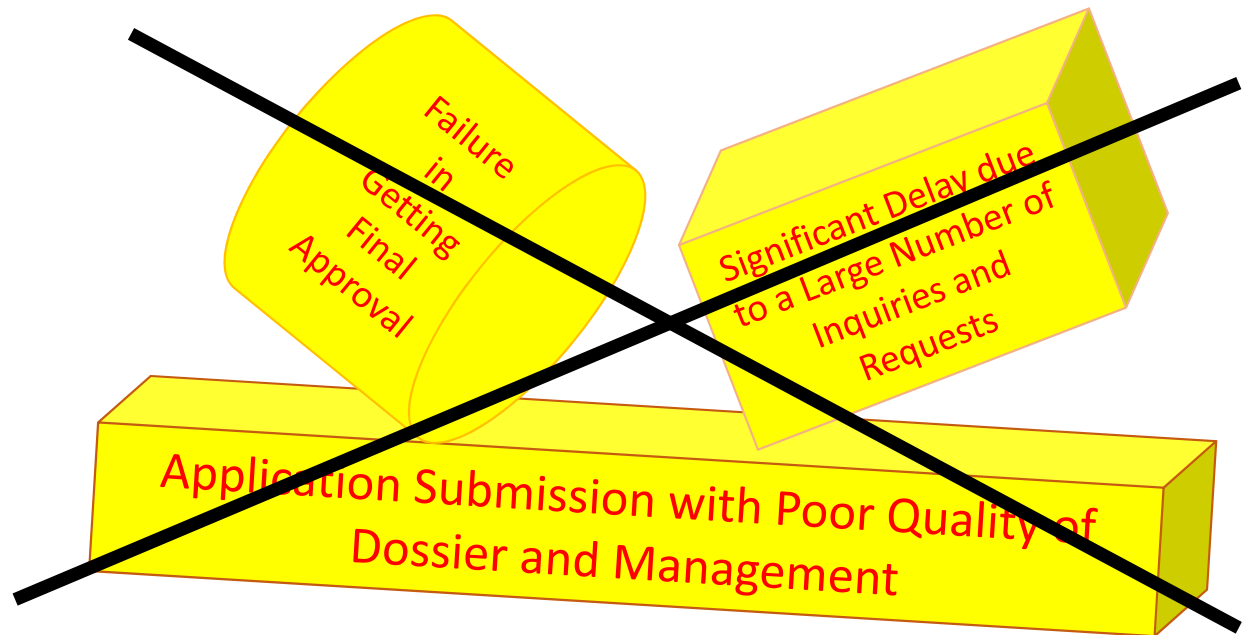


Common Session Lectures

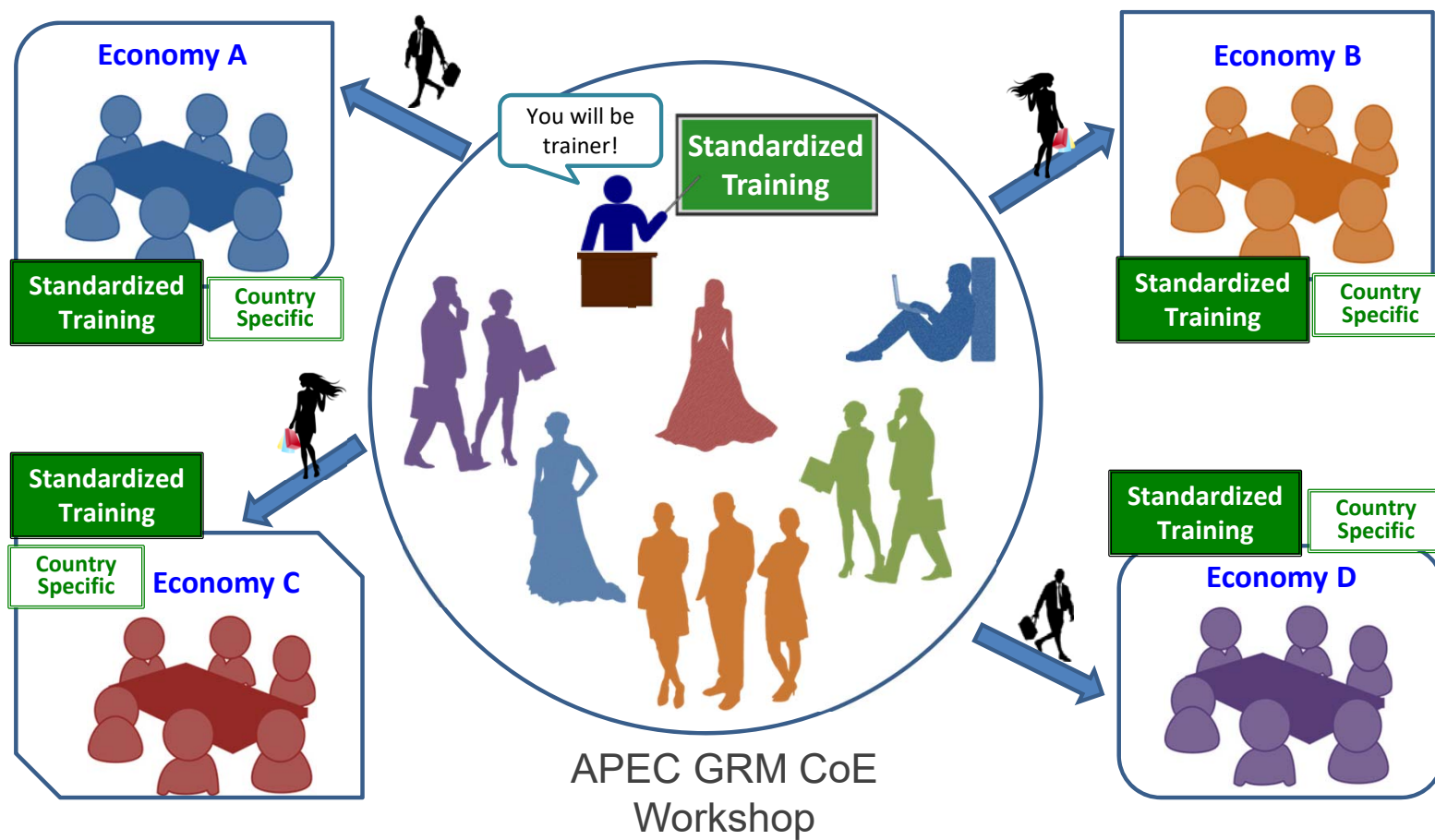


Dissemination

- Enhance efficiency and quality of medicinal product registration process
- Leads to expedite the launch of innovative medicines for the peoples in Asia



Train the Trainers



Trainings

- Singapore
 - 12 – 13 April, 2017
- Thailand
 - 26 – 28 June, 2018
- Malaysia
 - 4 – 5 July, 2018



Reporting on GRM in Singapore

Kum Cheun (KC) WONG

Presented on behalf of

Singapore Association of Pharmaceuticals Industries (SAPI)

GRM GSubP Team: Tricia Chean, Por Suat Gnoh, Sannie
Chong, Thean Soo Lo



GRM Good Submission Practice Workshop

Singapore, 12-13th April 2017



Tricia



Suat Gnoh



Sannie



TS



GRM Good Submission Practice Workshop

Singapore, 12-13th April 2017

HEALTH PRODUCTS
REGULATORY
CONFERENCE **2017**







In Conclusion

- ✓ GRM is the concept to promote both GRevP by regulators with GSubP by industry to enhance the quality and efficiency of the medical product registration process.
- ✓ GRM will improved evaluation, improve communication, reduce wastage of resource, improve timelines
- ✓ GSubP and GRevP complement each other, it is necessary to promote both GSubP and GRevP concomitantly in order to enhance overall quality and efficiency of medical product registration process
- ✓ **Ultimate Goal** to benefit patients with timely access to safe, efficacious and high quality medicines
- ✓ GSubP is industry's commitment to support improved efficiency of the Regulatory Review Process, to expedite access of safe, efficacious and high quality medicines to needy patients

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Summary & Expectation

- Collaboration with APEC brings Good Registration Management Center of Excellence
- Curriculum for Good Submission Practice are successfully developed as interactive
- Dissemination by “Train the Trainers” is implemented



To Expedite the Launch of Innovative Medicines
for the Peoples in Asia

Thank you very much!!

