Session 5:
Experiences Sharing from Other APEC Economies - Applicant

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1st Thailand GRM Conference
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Disclaimer

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to any organization with which the presenter is employed or affiliated.

APAC Asia PArtnership Conference of Pharmaceutical Associations

http://apac-asia.com/

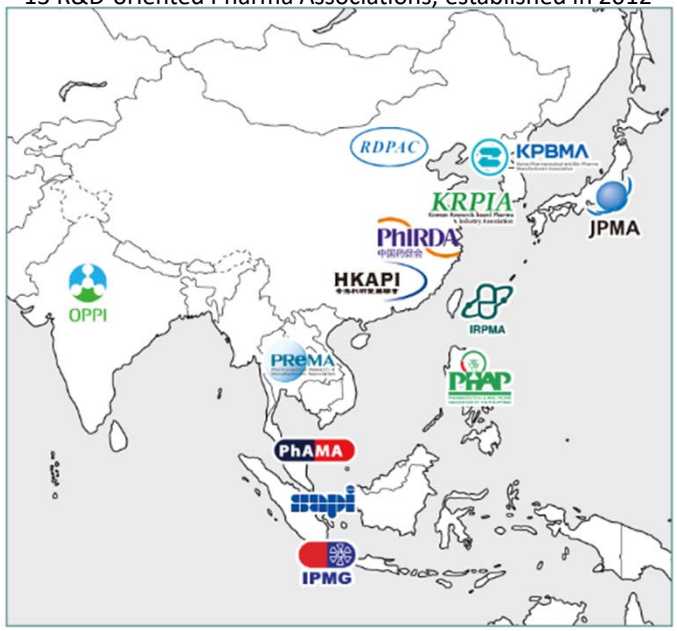
What is APAC?

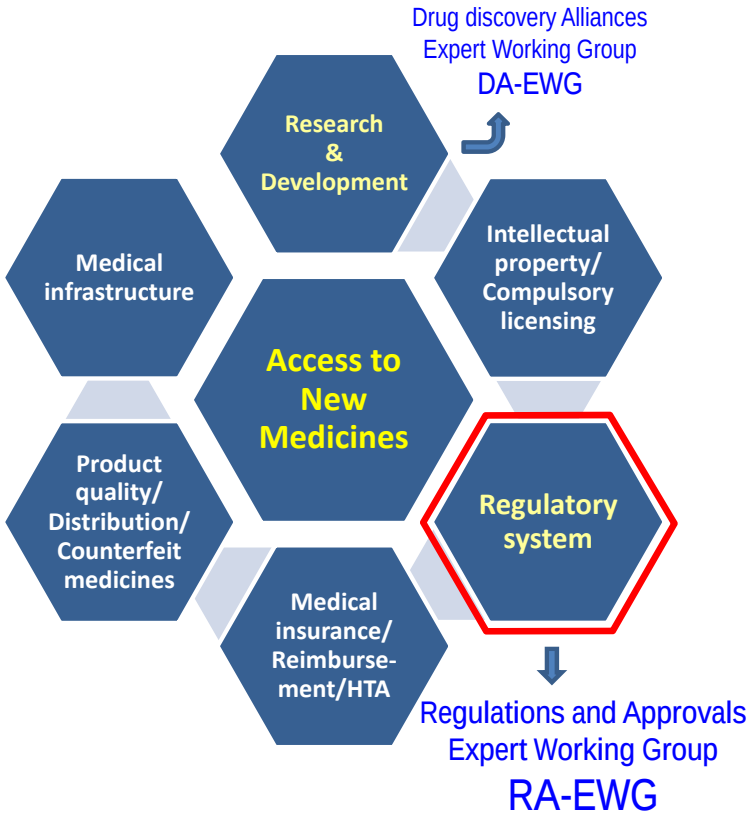
APAC =Asia Partnership Conference of Pharma Associations

Mission:

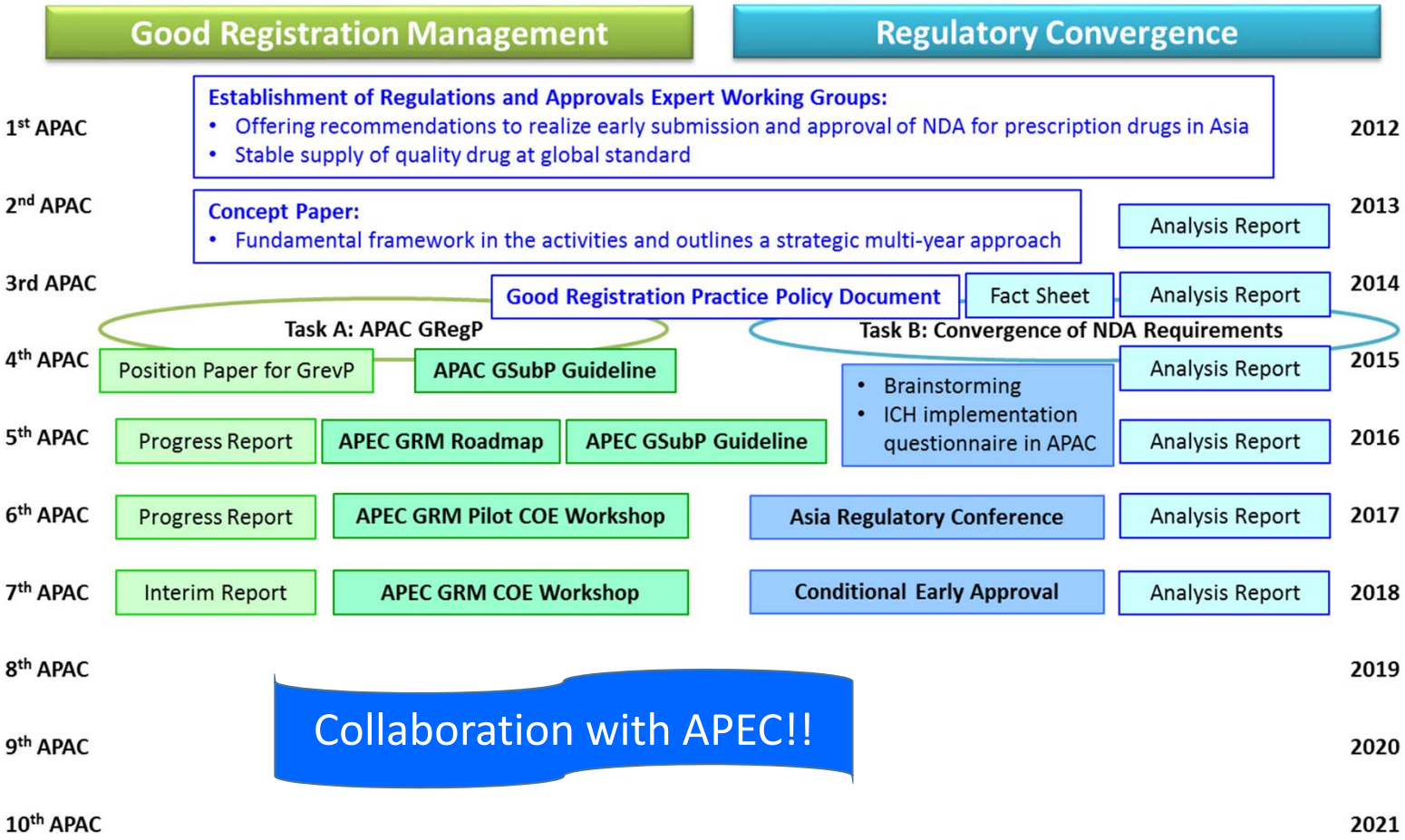
To Expedite the Launch of Innovative Medicines for the Peoples in Asia

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

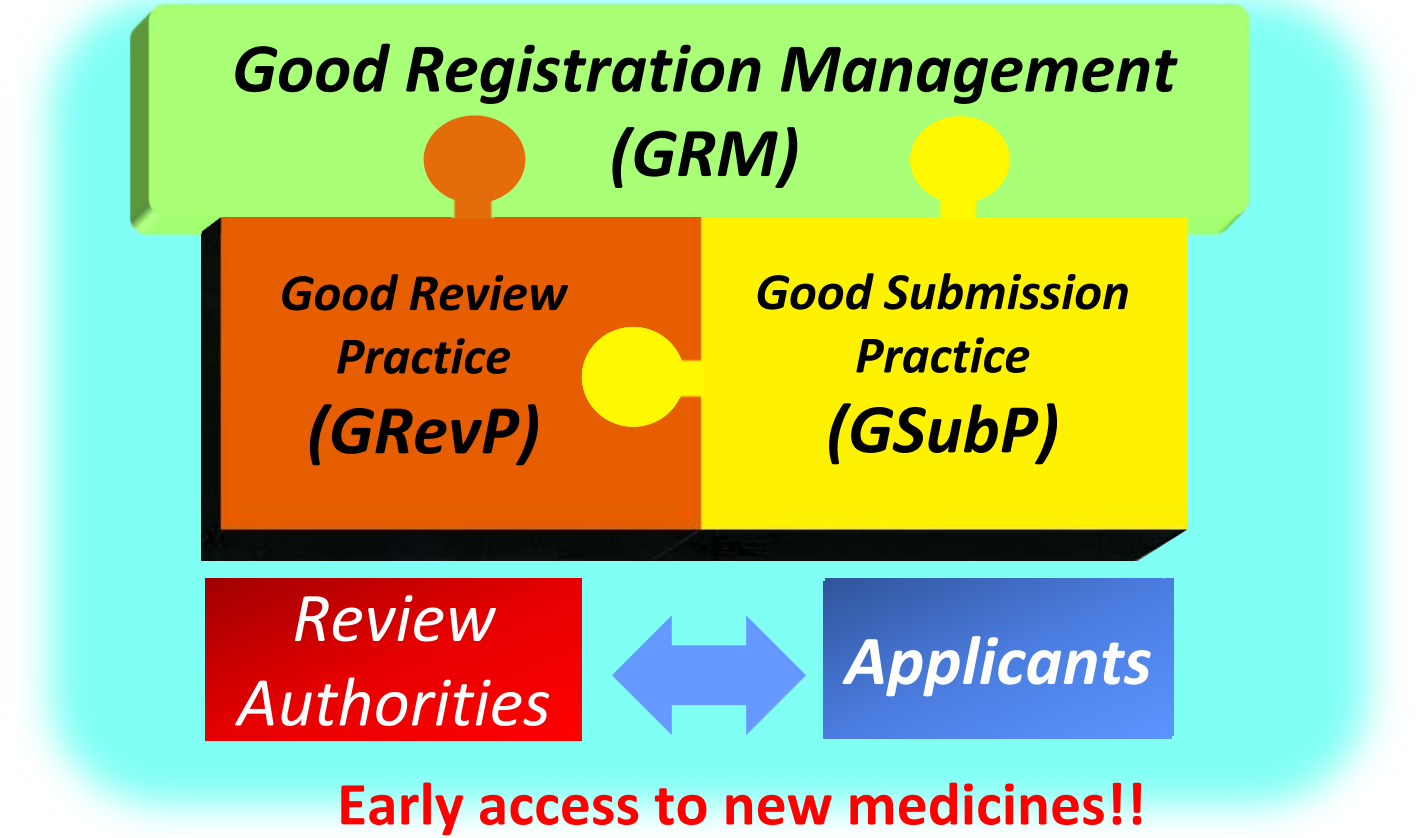




History of APAC RA-EWG



Mutual Success for Review Authorities and Applicants



GOOD SUBMISSION PRACTICE (GSubP) GUIDELINE FOR APPLICANTS

Point to Consider for training

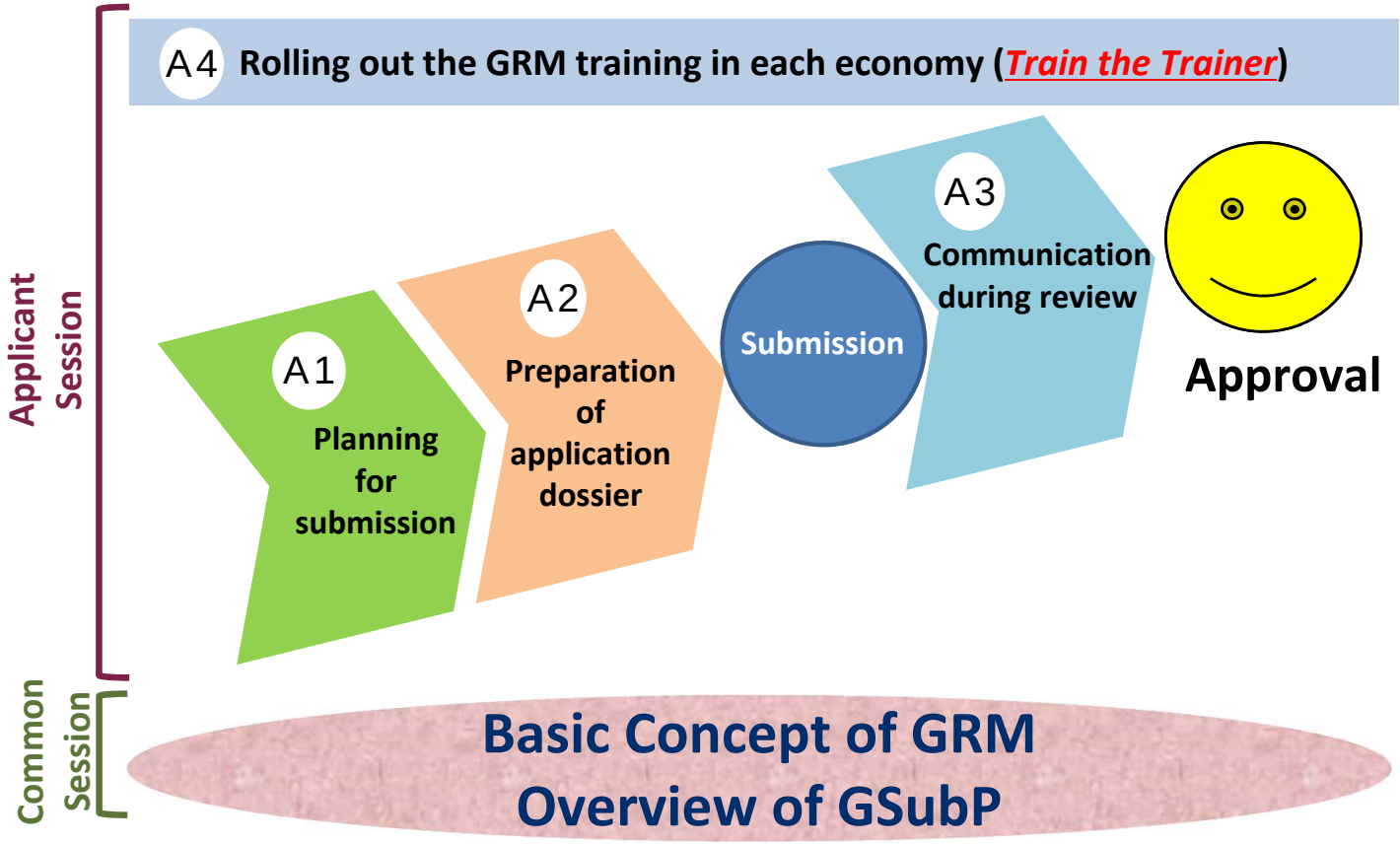
Style

- 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



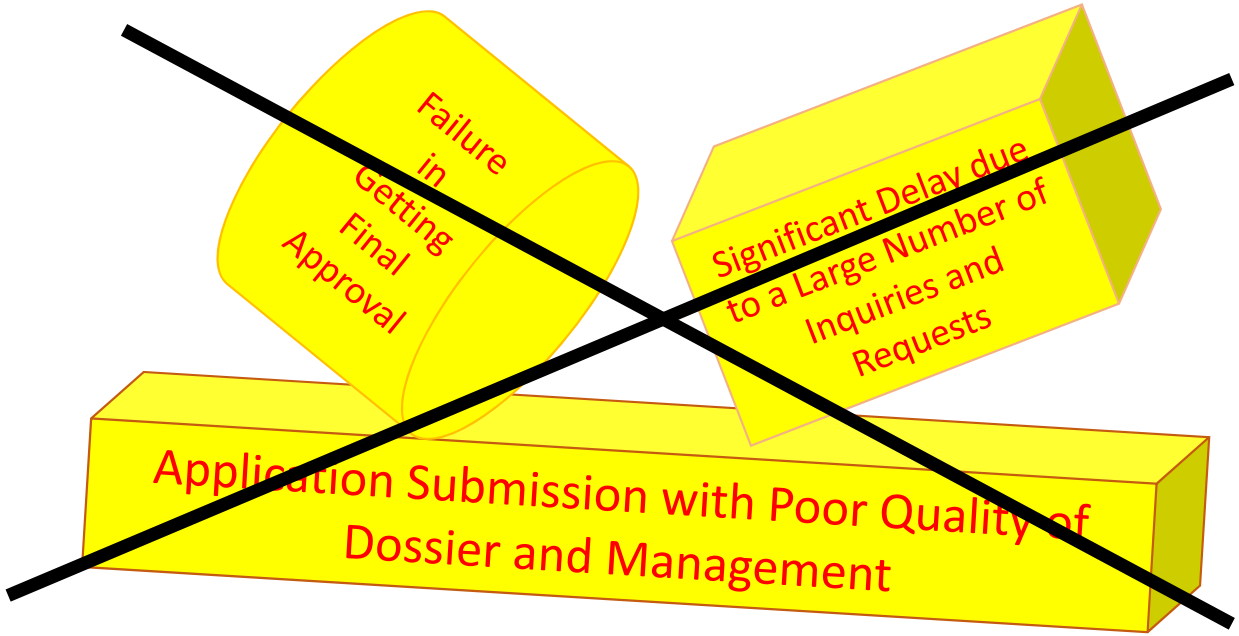
Photos

Applicant Session
Case Studies
Gr. Discussions
etc.

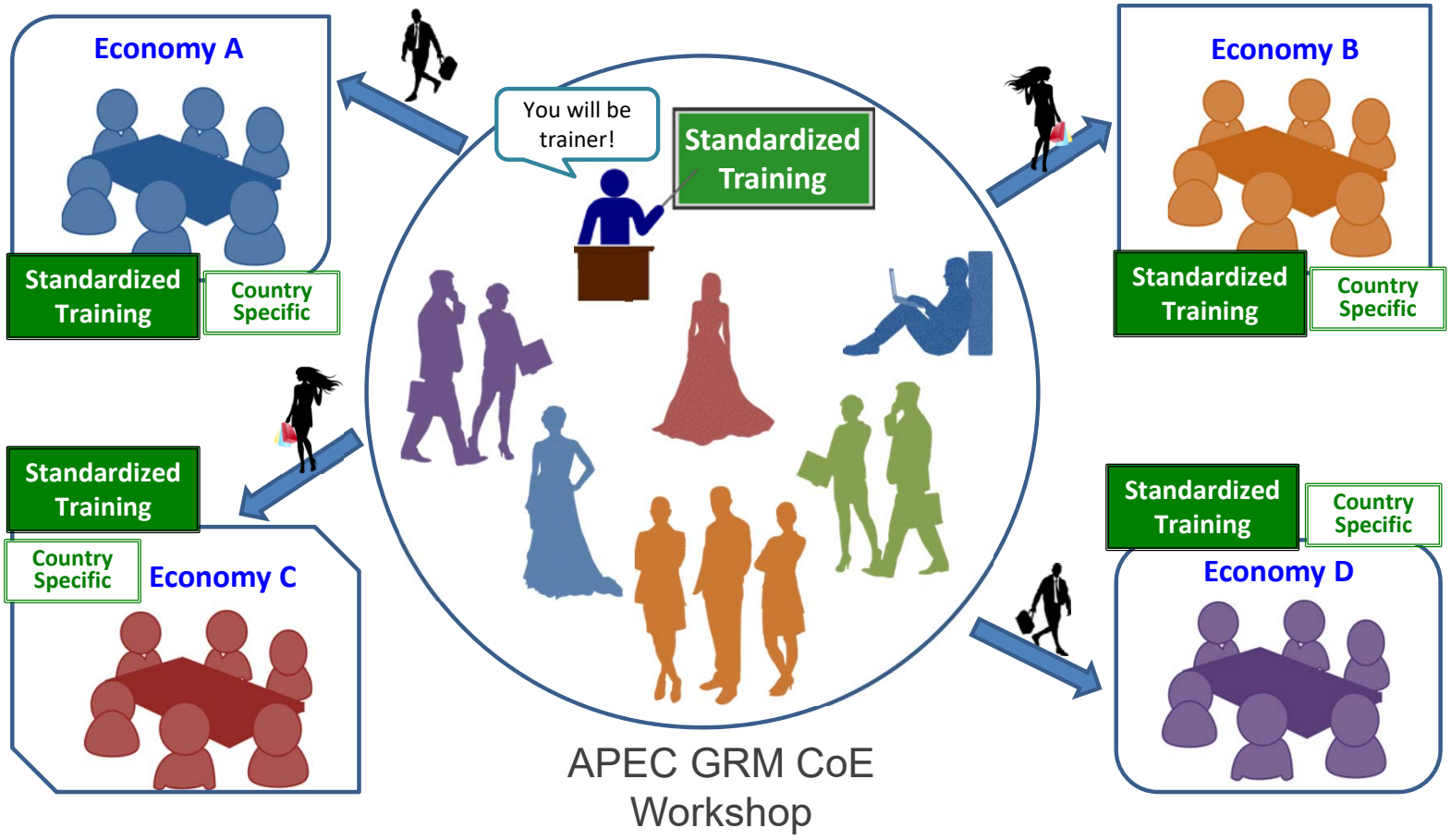
Common Session ***Lectures***

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

SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

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

SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

GRM Good Submission Practice Workshop

Singapore, 12-13th April 2017


Tricia


Suat Gnoh


Sannie


TS

SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

GRM Good Submission Practice Workshop

Singapore, 12-13th April 2017

HEALTH PRODUCTS REGULATORY CONFERENCE 2017

DukeNUS Medical School | CoRE | HSA

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!!