NATIONAL REGULATORY CONFERENCE 2015
Day 3, Plenary 9

New Initiative for Good Registration Management from Industry Perspective - Enhancing Good Submission Practices by APAC

August 6, 2015

APAC RA-EWG Director
Kiminori Nagao

APAC
Asia Partnership Conference of Pharmaceutical Associations

Topics

1. **Asia Partnership Conference of Pharmaceutical Associations (APAC)**
2. Concept of GRM
3. GRevP Guideline
4. APAC GSubP Guideline
5. DRAFT Roadmap of GRM Training
6. APAC position paper
7. Summary

GRM: Good Registration Management
GSubP: Good Submission Practice
GRevP: Good Review Practice

APAC
Asia Partnership Conference of Pharmaceutical Associations

What is APAC?

APAC

Asia Partnership Conference of Pharmaceutical Associations

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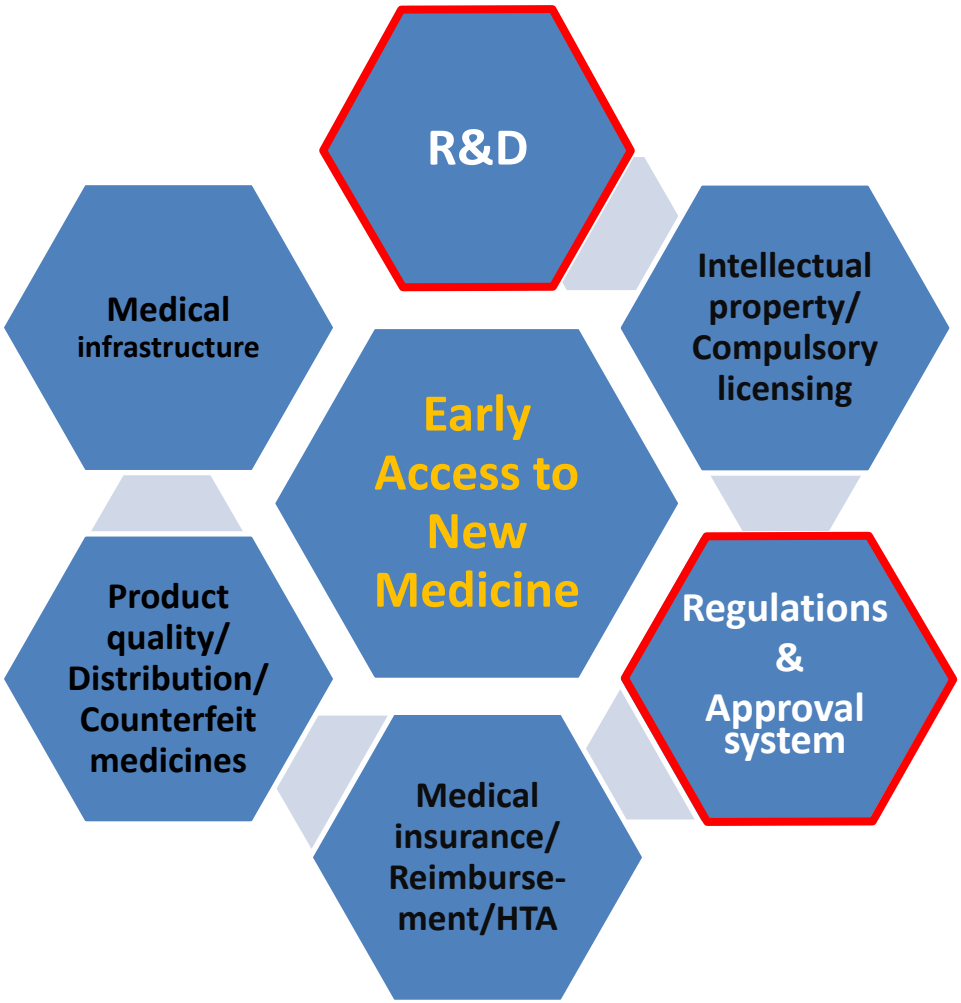
APEC

Asia-Pacific Economic Cooperation

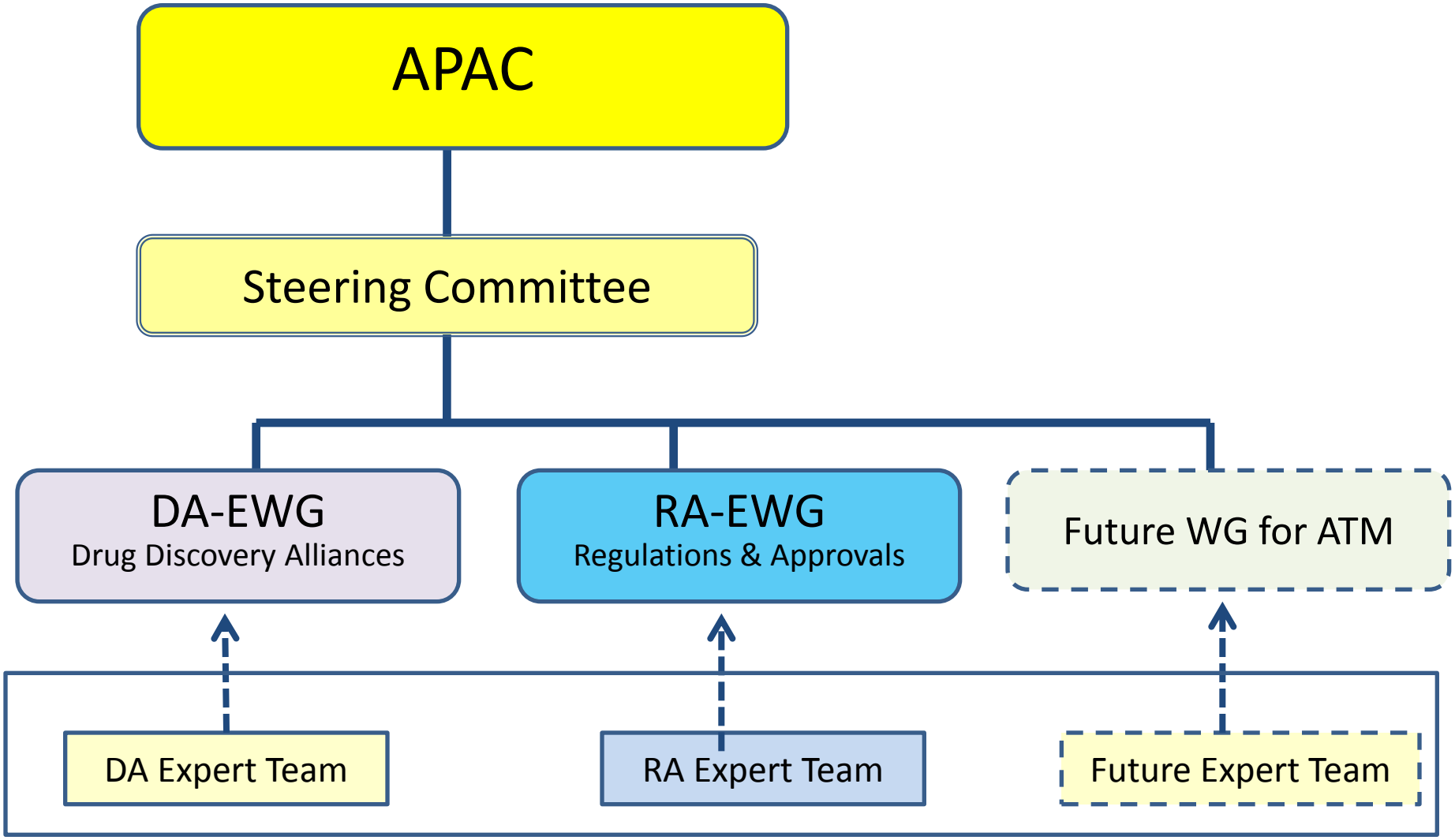
4th APAC in Apr. 2015 in Tokyo

Mission

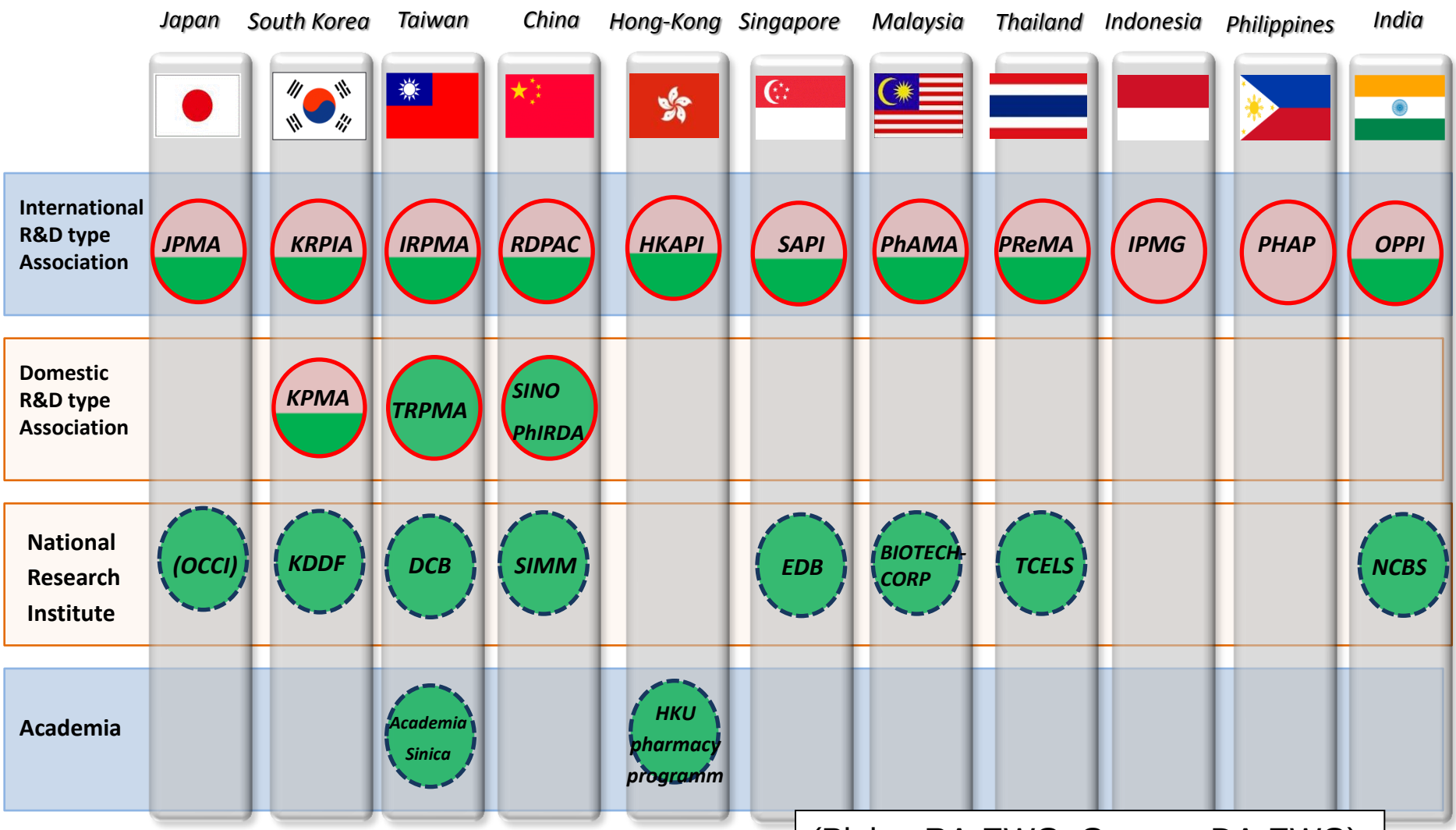
"To expedite the launch of innovative medicines for the peoples in Asia"



APAC Organization



APAC Members



(Pink = RA-EWG, Green = DA-EWG)

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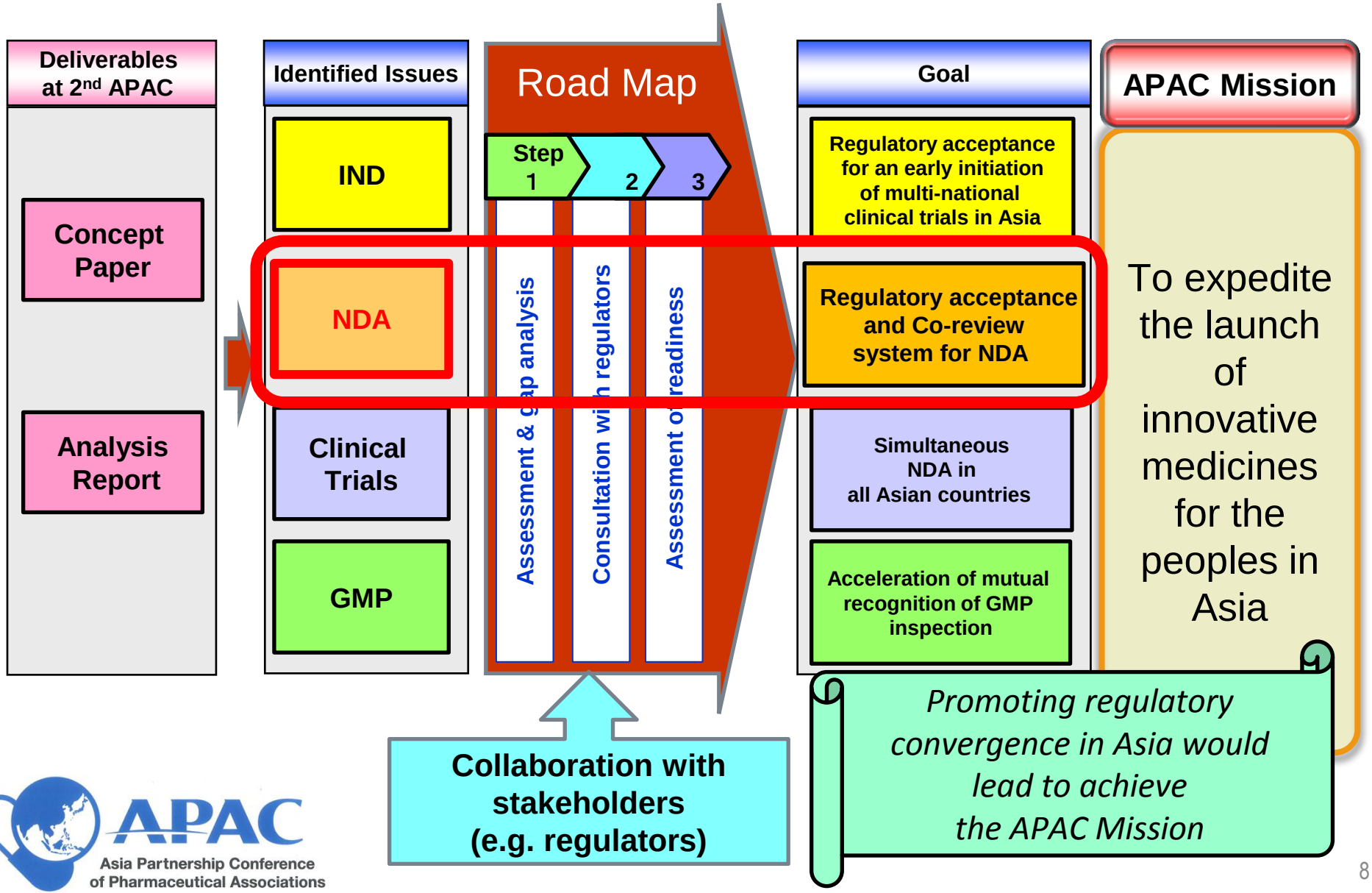
APAC RA-EWG Direction



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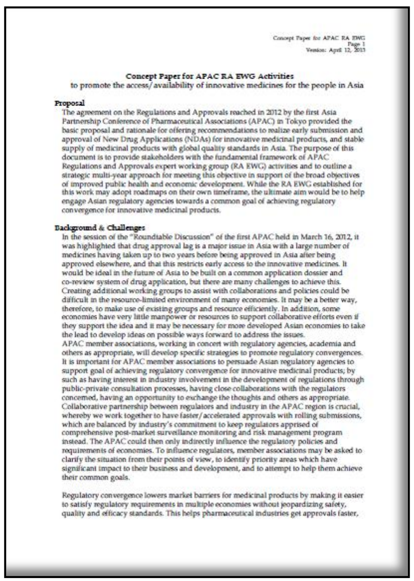
1st Deliverables: RA-EWG in 2nd APAC (Apr. 2013)

Concept Paper

- provides fundamental framework in the activities of RA-EWG and outlines a strategic multi-years approach



Concept Paper for APAC RA EWG
Page 1
Version: April 12, 2013

Concept Paper for APAC RA EWG Activities
to promote the access/availability of innovative medicines for the people in Asia

Proposal

The agreement on the Regulations and Approvals reached in 2012 by the first Asia Partnership Conference of Pharmaceutical Associations (APAC) in Tokyo provided the basic proposal and rationale for offering recommendations to realize early submission and approval of New Drug Applications (NDAs) for innovative medicinal products, and stable supply of medicinal products with global quality standards in Asia. The purpose of this document is to provide stakeholders with the fundamental framework of APAC Regulations and Approvals expert working group (RA EWG) activities and to outline a strategic multi-year approach for meeting this objective in support of the broad objectives of improved public health and economic development. While the RA EWG established for this work may adopt roadmaps on their own timeframe, the ultimate aim would be to help engage Asian regulatory agencies towards a common goal of achieving regulatory convergence for innovative medicinal products.

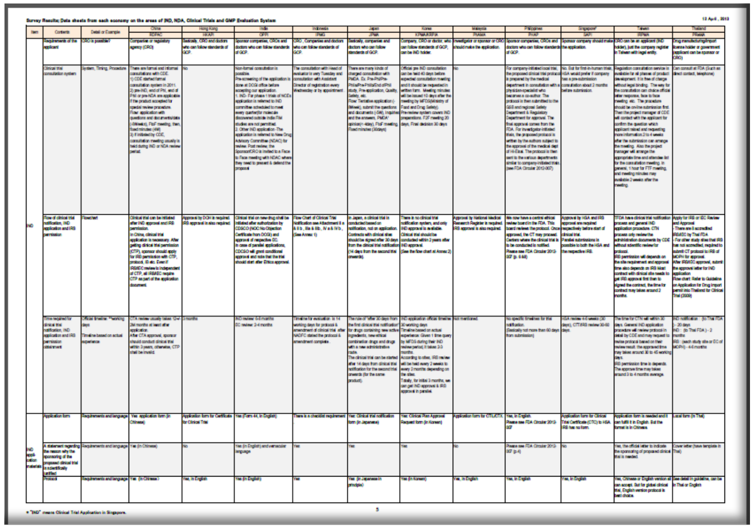
Background & Challenges

In the session of the "Roundtable Discussion" of the first APAC held in March 16, 2012, it was highlighted that drug approval lag is a major issue in Asia with a large number of medicines having taken up to two years before being approved in Asia after being approved elsewhere, and that this restricts early access to the innovative medicines. It would be ideal in the future of Asia to be built on a common application dossier and co-review system of drug application, but there are many challenges to achieve this. Creating additional working groups to assist with collaborations and policies could be difficult in the resource-limited environment of many economies. It may be a better way, therefore, to make use of existing groups and resource efficiently. In addition, some economies have very little manpower or resources to support collaborative efforts even if they support the idea and it may be necessary for more developed Asian economies to take the lead to develop ideas on possible ways forward to address the issues.
APAC member associations, working in concert with regulatory agencies, academia and others as appropriate, will develop specific strategies to promote regulatory convergences. It is important for APAC member associations to persuade Asian regulatory agencies to support goal of achieving regulatory convergence for innovative medicinal products; by such as having interest in industry involvement in the development of regulations through public-private consultation processes, having close collaborations with the regulators concerned, having an opportunity to exchange the thoughts and others as appropriate. Collaborative partnership between regulators and industry in the APAC region is crucial, whereby we work together to have faster/accelerated approvals with rolling submissions, which are balanced by industry's commitment to keep regulators apprised of comprehensive post-market surveillance monitoring and risk management program instead. The APAC could then only indirectly influence the regulatory policies and requirements of economies. To influence regulators, member associations may be asked to clarify the situation from their points of view, to identify priority areas which have significant impact to their business and development, and to attempt to help them achieve their common goals.

Regulatory convergence lowers market barriers for medicinal products by making it easier to satisfy regulatory requirements in multiple economies without jeopardizing safety, quality and efficacy standards. This helps pharmaceutical industries get approvals faster,

Analysis Report

- identifies differences in regulatory requirements on drug development from IND, clinical trials, NDA and manufacturing/post approval



http://www.jpma.or.jp/english/apac/2nd_apac.html

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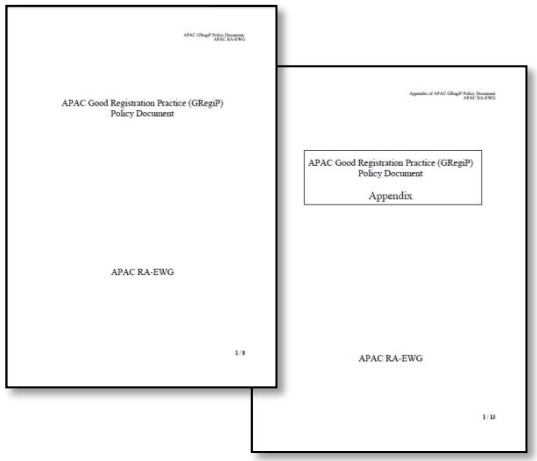
2nd Deliverables: RA-EWG in 3rd APAC (Apr. 2014)

Task A: Good Registration Management

Policy Document & Appendix

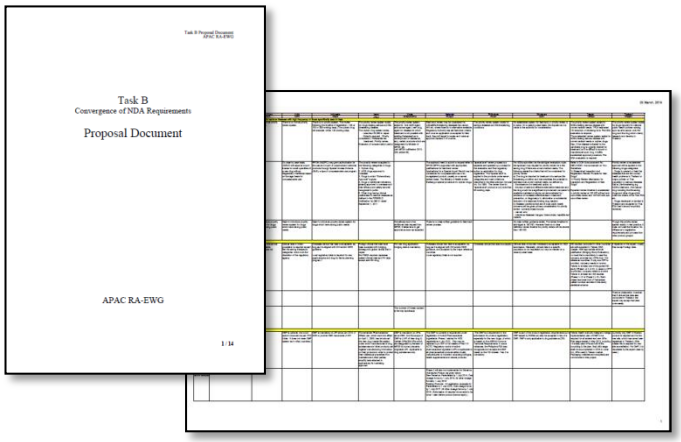
- describe basic concept & policy of Good Registration Management with several practical proposals



Task B: Convergence of NDA Requirements

Proposal Document & Fact Sheet

- describe issues and proposed approaches to improve regulatory requirements for NDA.



http://www.jpma.or.jp/english/apac/3rd_apac.html

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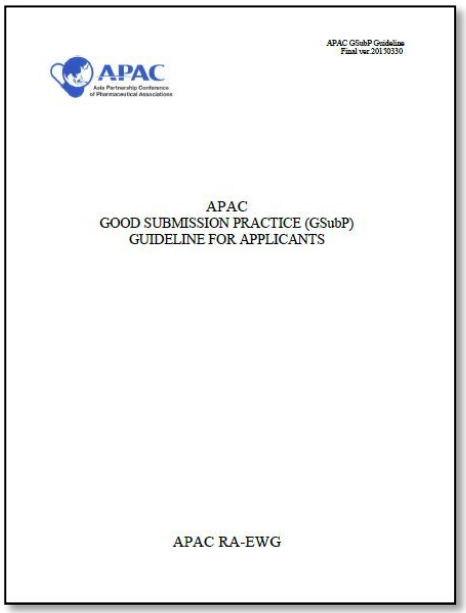
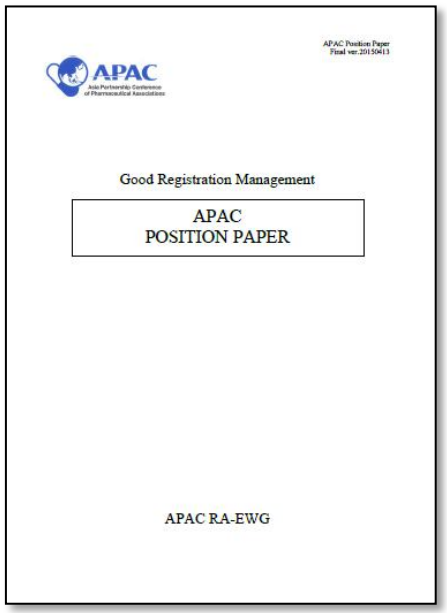
3rd Deliverables: RA-EWG in 4th APAC (Apr. 2015)

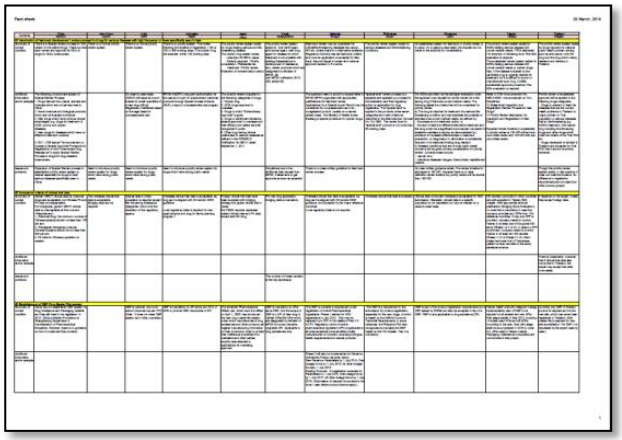
APAC GSubP Guideline



APAC Position Paper



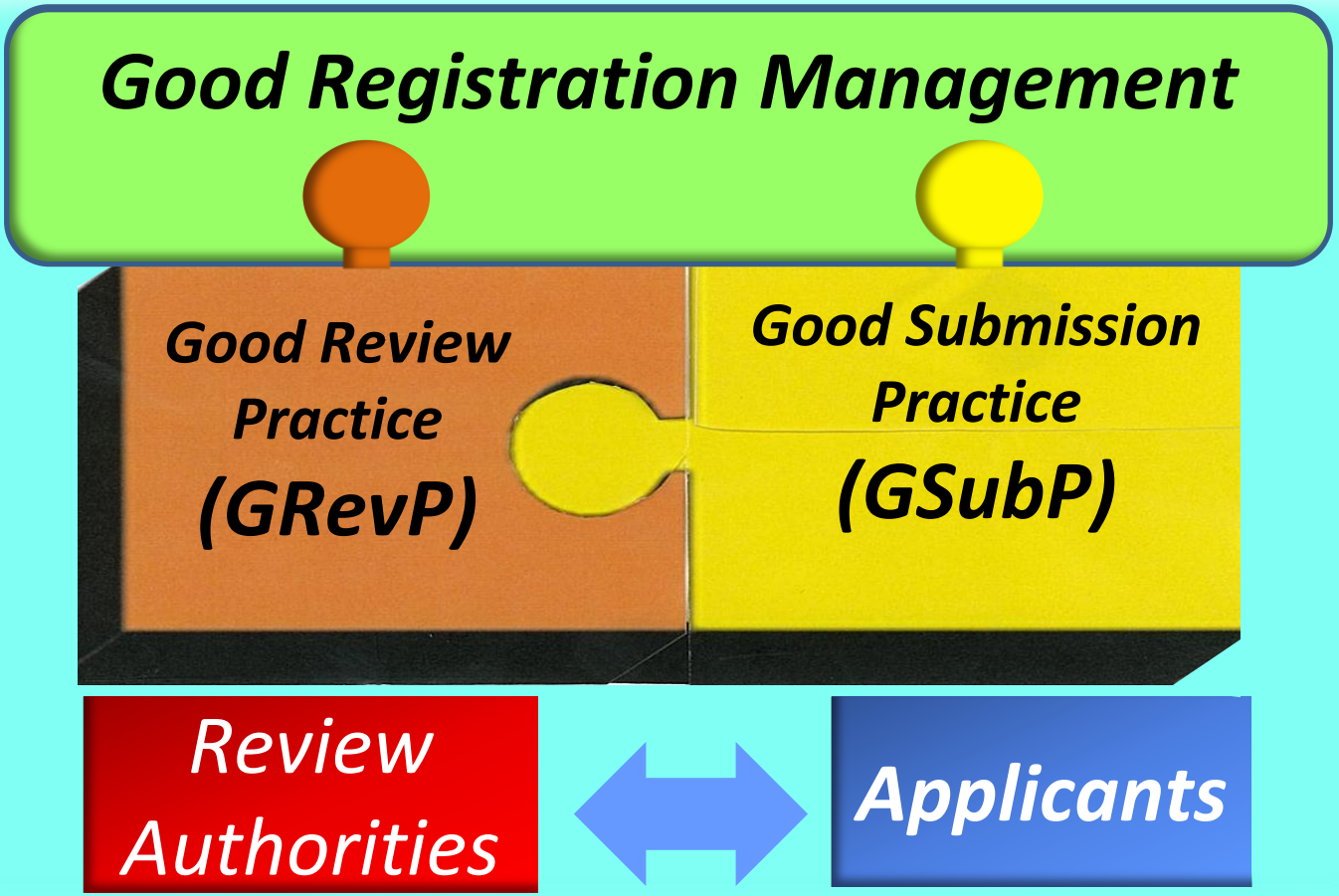
Analysis Report



Asia Partnership Conference of Pharmaceutical Associations

http://www.jpma.or.jp/english/apac/4th_apac.html

Mutual Success for Review Authorities and Applicants



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Early access to new medicines!!

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Global Consultation of Draft Guidelines

Working document QAS/14.576 Rev.1
August 2014
Document for comment

World Health Organization

Good review practices

guidelines for regulatory authorities

(August 2014)

DRAFT FOR COMMENT

Should you have any comments on the attached text, please send these to: Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies, Standards and Norms, World Health Organization, 1211 Geneva 27, Switzerland; email: koppss@who.int; fax: (+41 22) 791 4730 (koppss@who.int) and to Ms Marie Gaspard (gaspardm@who.int), by 30 September 2014.

Working documents are sent out electronically and they will also be placed on the Medicines website for comment. If you do not already receive directly our draft guidelines please let us have your email address (to bonnyn@who.int) and we will add it to our electronic mailing

SCHEDULE FOR THE ADOPTION PROCESS OF DOCUMENT QAS/14.576

Good review practices guidelines for regulatory authorities

	Date
Draft document endorsed by APEC Regulatory Harmonization Steering Committee (RHSC) for submission to WHO	21 February 2014
Accepted internally for parallel consultative processes for both the WHO Expert Committee on Specifications for Pharmaceutical Preparations and the WHO Expert Committee on Biological Standardization	21 February 2014
Draft mailed for comments	March 2014
Collation of comments	April-May 2014
Reviewed/revised in consultation with APEC	May-August 2014
Circulation for comments	August 2014
Collation of additional comments, if any	September 2014
Presentation to forty-ninth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations	13-17 October 2014
Further follow-up action as required	…

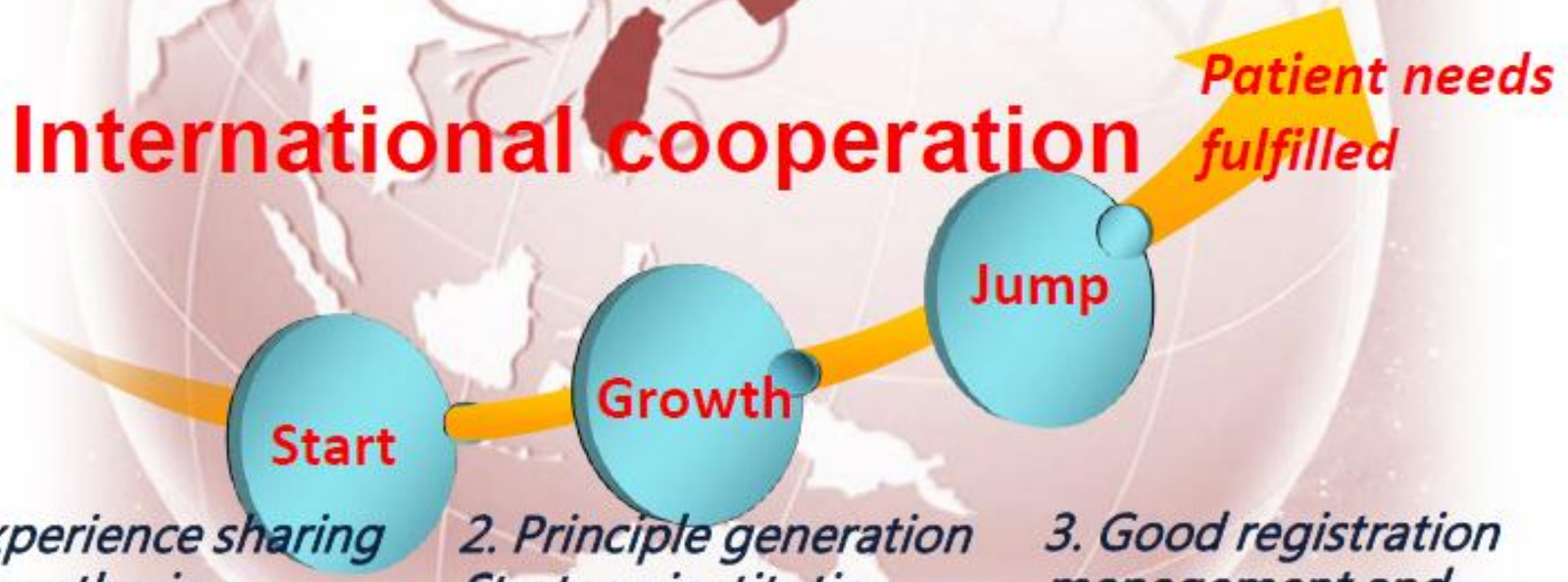
In partnership with APEC RHSC, WHO completed the global consultation and presented the draft guidelines to the WHO Expert Committees, both ECSPP and ECBS meetings held 13-17 October 2014.

http://www.who.int/medicines/areas/quality_safety/quality_assurance/projects/en/

Contents of Good Review Practices Guidelines for Regulatory Authorities

Good Submission Practice

International cooperation



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APAC GSubP Guideline: Table of Contents

APAC GSubP Guideline for Applicants

1. INTRODUCTION
2. PRINCIPLES OF GOOD SUBMISSION
3. MANAGEMENT OF SUBMISSION
4. COMMUNICATIONS
5. COMPETENCY AND TRAINING
6. GLOSSARY
7. REFERENCES

GRevP guidelines for regulatory authorities
WHO Draft for comment (Aug 2014)

1. INTRODUCTION
2. PRINCIPLES OF GOOD REVIEW
3. MANAGING THE REVIEW
4. COMMUNICATIONS
5. REVIEW PERSONNEL
6. CONDUCTING THE REVIEW
7. GLOSSARY
8. REFERENCES

Outline of APAC GSubP Guideline

Scope:

- ***Setting out general and high level guidance*** *for applicants to make good submission*
- ***Focusing on NDA*** *of human drugs including line extensions (e.g., new indication, dosage)*
- *Covering the whole product registration process from* ***development, submission and review stages up to approval***
- *Aiming to* ***balance what applicants should do with what reviewers could also keep in mind***

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2. PRINCIPLES OF GOOD SUBMISSION

1. *Strong Scientific Rationale and Robust Data with Clarification of Benefit-Risk Profile*
2. *Compliance to Up-to-date Regulatory Requirements*
3. *Well-Structured Submission Dossier with Appropriate Cross-references*
4. *Reliability, Quality, Integrity and Traceability of Submission Documents and Source Data*
5. *Effective and Efficient Communications*

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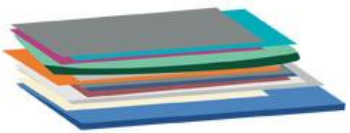
3. MANAGEMENT OF SUBMISSION

- *Planning for submission*
  - *Start discussion on submission strategy from **early stage of product development***
  - *Use **support tools** effectively e.g. check-list, template, glossary*
- *Preparation and Submission of Application Dossier*
  - *Provide general instructions on **report/summary writing, compiling and submission***
  - *Encourage creating **SOPs***
- *Quality Check*
  - *Provide instructions on QC at writing/revision/translation for,*
    - ✓ ***Study reports and summary documents***
    - ✓ ***Submission dossier, Electronic dossier***



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4. COMMUNICATIONS

- *Communications with review authorities*
  - *Make effective use of **pre-/post- submission meetings***
  - *Manage **inquiry and response** appropriately*
    e.g. clarifications, timeline management
- *Communications amongst applicants*
  - *Confirm **operation model, role and responsibility** of the submission team & members*
  - *Establish **standard working procedure and communication platform***

4. COMPETENCY AND TRAINING

- *Core Competency of Applicants*
  - ***Scientific knowledge and expertise***
  - ***Good understanding of up-to-date regulations***
  - *Other hard and soft skills, e.g. Planning & PJ management, medical writing, IT skills for e-submission, problem solving, communication*
  - ***Integrity, reliability and ethical standards***

- *Training and Capacity Building*
  - *Participate in **external training programs***
  - *Gain experiences through **day-to-day operations,** e.g. in-house training, self-training, OJT*
  - *Create and use **archive of experiences and knowhow***

Next steps for GSubP Guideline

2015

- Share the updated GSubP at the APEC RHSC (Aug. 2015)
  - ➢ Expanded the scope of GSubP: Beyond Asia (reviewed thru IFPMA) & added other medical products
- Dissemination of the concept of GSubP through Conference, Symposium, Workshop and Seminar

2016 -

- Finalization of GSubP in align with GRevP

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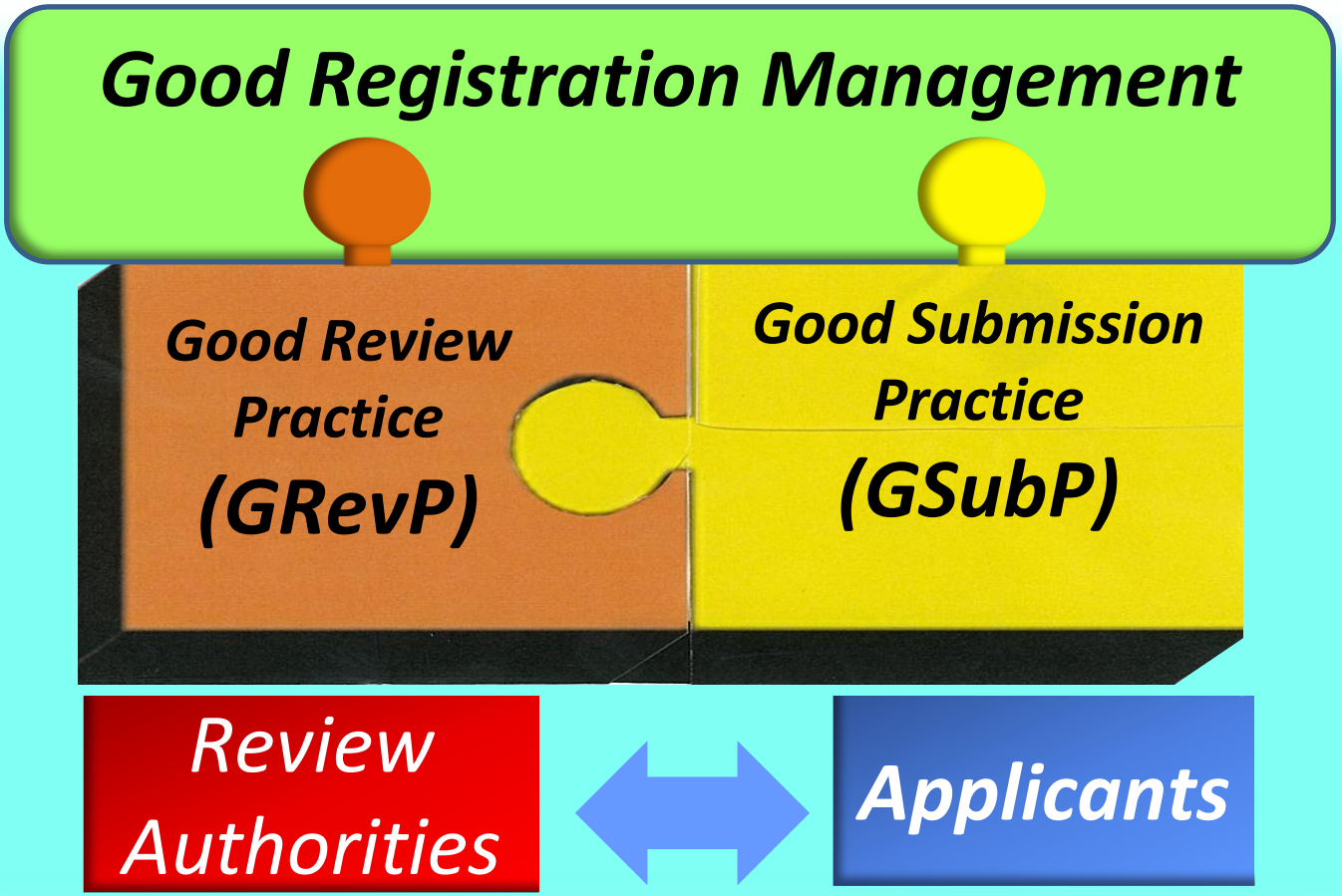
Concept of Good Registration Management



Specific Activities and Timeframe of GRevP Roadmap

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 gap analysis survey

Step 2 (2011-2014)

Planned Solution to Address Gap

Training
Develop Normative GRevP document → **Develop WHO Guidelines**
Set up quality management system (QMS) within interested economies
Establish a network of GRevP
Conduct pilot studies for regulatory information exchange

Step 3 (2012-2015)

Assessing the Impact of GRevP Training and Exchange of Regulatory Information

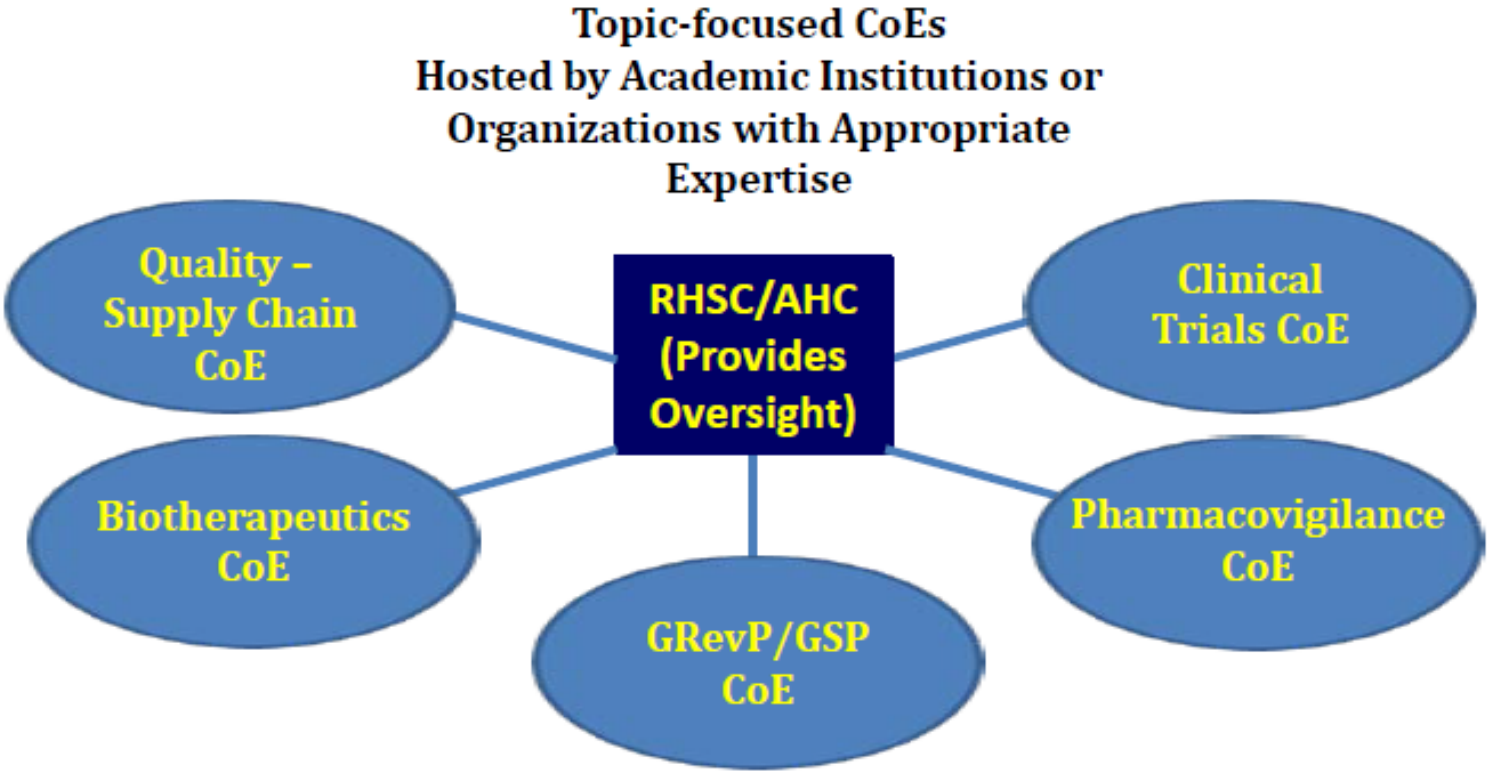
Step 4 (2015-2020)

Reaching the Goal for Achieving Common Regulatory Elements

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

衛生福利部 食品藥物管理署 FDA Food and Drug Administration

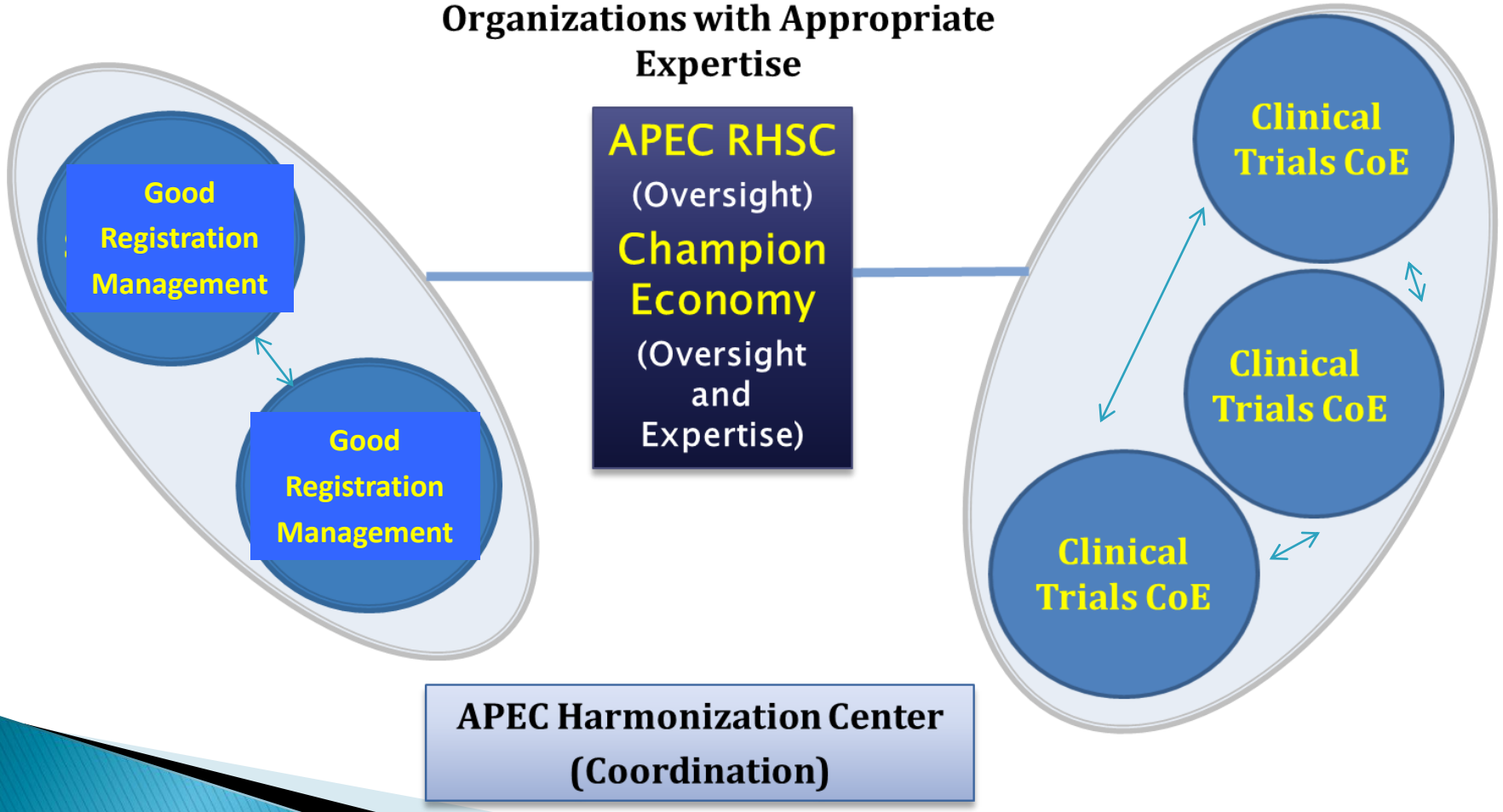
Draft Concept Model for APEC Training Center of Excellence for Regulatory Science (CoE)



APEC CoE Draft Model

Networks of CoEs for a topic area are possible;
GLOBAL model
(Are networks connected?)

Topic-focused CoEs
Hosted by Academic Institutions or Organizations with Appropriate Expertise



DRAFT: Structure of GRM* training curriculum

* Good Registration Management (GRevP & GSubP)

GRM Common Training

- Basic Concept of GRM
- Outline of GRevP Guideline
- Outline of GSubP Guideline

Reviewer Specific Training

- ✓ To be developed in each review authority
- ✓ Based on current review system/procedure

Applicant Specific Training

- ✓ To be developed in each country/area by industry association
- ✓ Based on requirements of application submission

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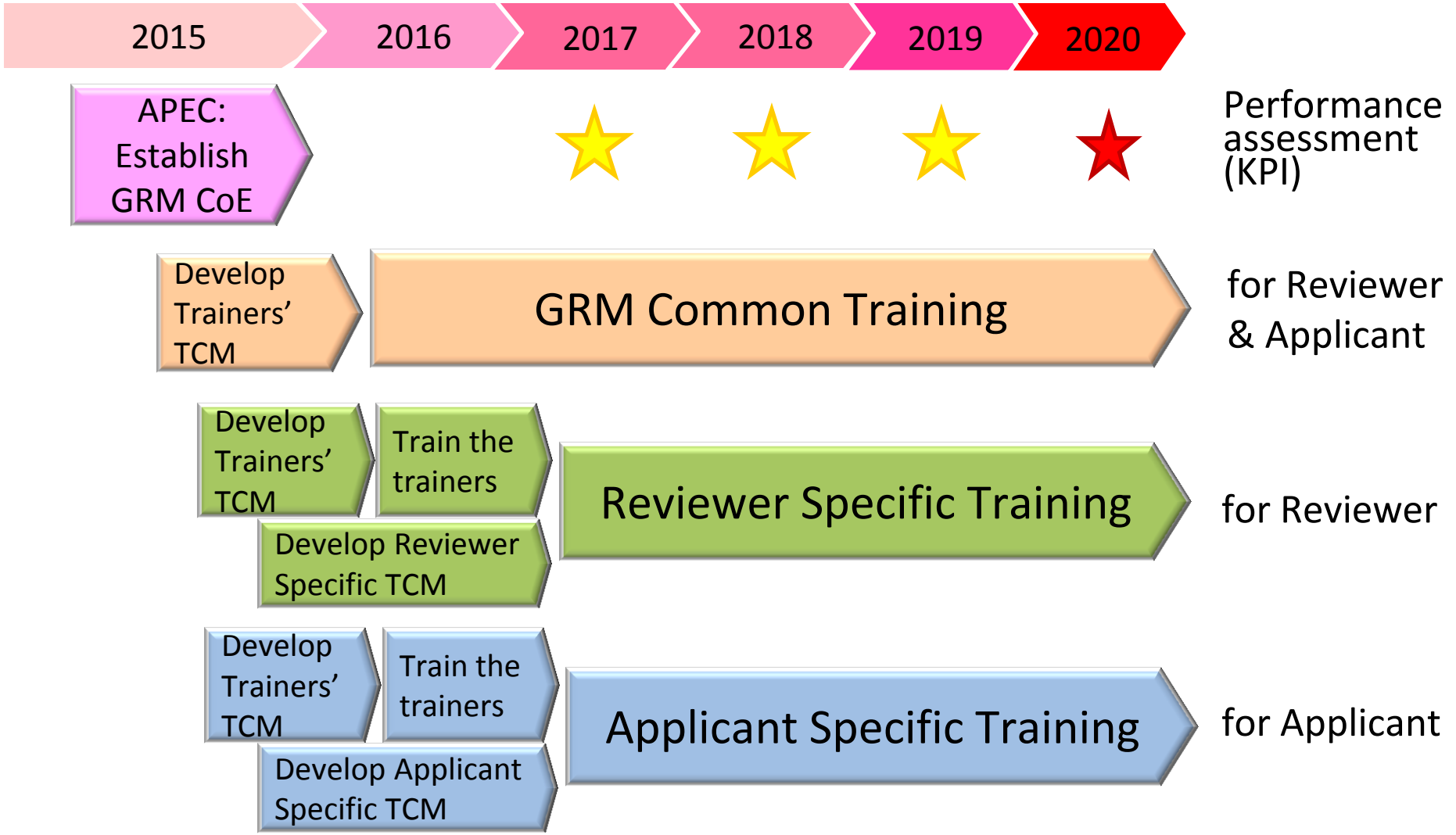
DRAFT: High-level Roadmap of GRM Training



TCM*: Training Curriculum & Material

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APAC Position Paper

- Supporting promotion of GRevP and GSubP
- Making practical proposals from industry perspectives
  - ✓ Goal
  - ✓ Proposed Option
  - ✓ Expected Effect

Road to future regulatory convergence and work sharing of drug review in Asia

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APAC proposals in the Position Paper

#1: Establishing structured framework to support ***regulatory consultation***

#2: Facilitating ***transparency to review policy, standards, draft regulations, guidelines and new initiative from regulatory authority***

#3: Facilitating transparency to ***review process and status***

#4: Facilitating ***collaborative training program and workshop*** between the regulatory authorities and industry

#5: Facilitating ***generation of review report in English***

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Difference of regulatory circumstances in Asia

	Regulatory consultation system				Review process tracking system	
	Formal	Informal	Binding	Written Guidance	Setting timeline	Tracking system
A	✓	✓	Unclear	✓	✓ (some issues)	✓
B		✓				
C	✓	✓	Unclear	✓ (draft)		
D	✓	✓		✓ (letter)	✓	
E	✓	✓	Case by case	✓	✓	
F	✓	✓	Case by case		✓	✓
G		✓			✓ (partly)	
H		✓				✓ (some issues)
I	✓	✓		✓	✓	✓
J		✓			✓	✓ (NDA only)
K		✓	Case by case		✓	✓ (some issues)

✓: Yes/ Implemented
Blank: Not implemented

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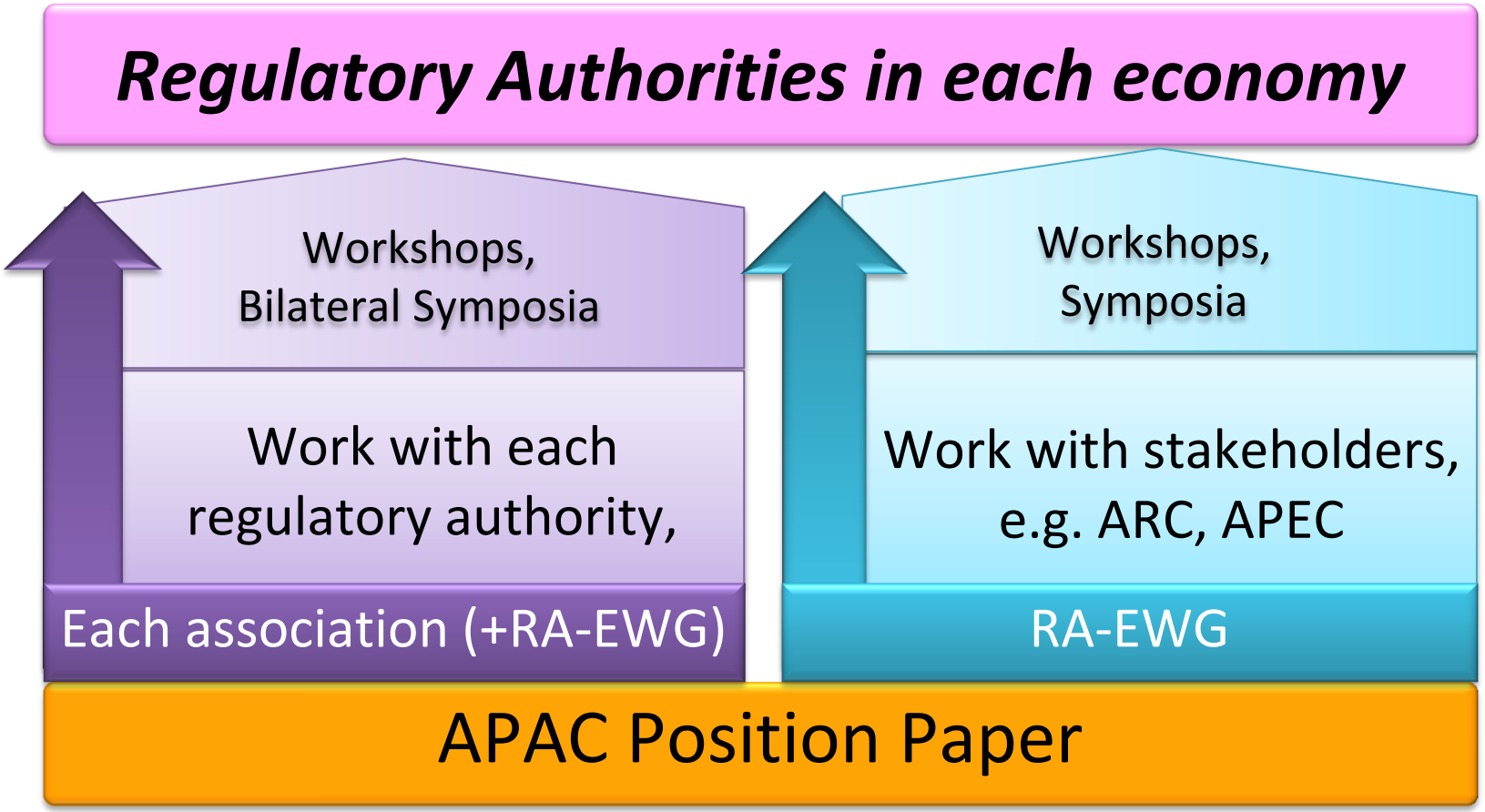
Approach to Regulatory Authorities (2015 -)



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RA-EWG Activities and Future Goal
- Promotion of Good Registration Management

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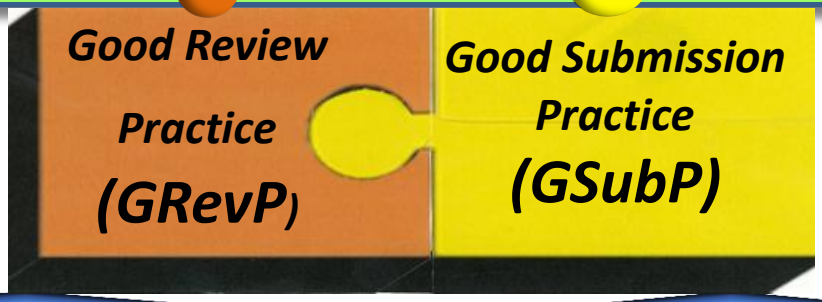
Realize early access to new medicines for peoples in Asia

Enhance efficiency of NDA review

Good Registration Management



Make proposals to support facilitation of GRevP

Improve quality of submission and its management

APAC Position Paper

- *Further improvement in transparency, predictability and timeliness of review by facilitating communication*

- *Reduced number of critical deficiencies*
- *Decrease of rejections*

APAC GSubP Guideline

What we expect by enhancing GSubP

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For review authorities

1. No need to make unnecessary inquiry
2. Possible to focus on key points/issues during review
3. Possible to enhance efficiency and timeliness of review

For applicants

1. Risk of rejection and number of critical/major deficiencies will be reduced
2. Possible to gain reputation and trust in high quality submission
3. Possible to obtain early approval

Enhance efficiency and quality of product registration process


Terima kasih!
Thank you !