Regulations and Approvals Session
Presentation-2

Report of APAC RA-EWG activities

April 7, 2016

APAC RA-EWG Director
Kiminori Nagao

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Topics

1. **Good Submission Practice (GSubP) Guideline**
2. **Good Registration Management (GRM) Roadmap and GSubP training plan**
3. **Task A progress report**
4. **Summary**

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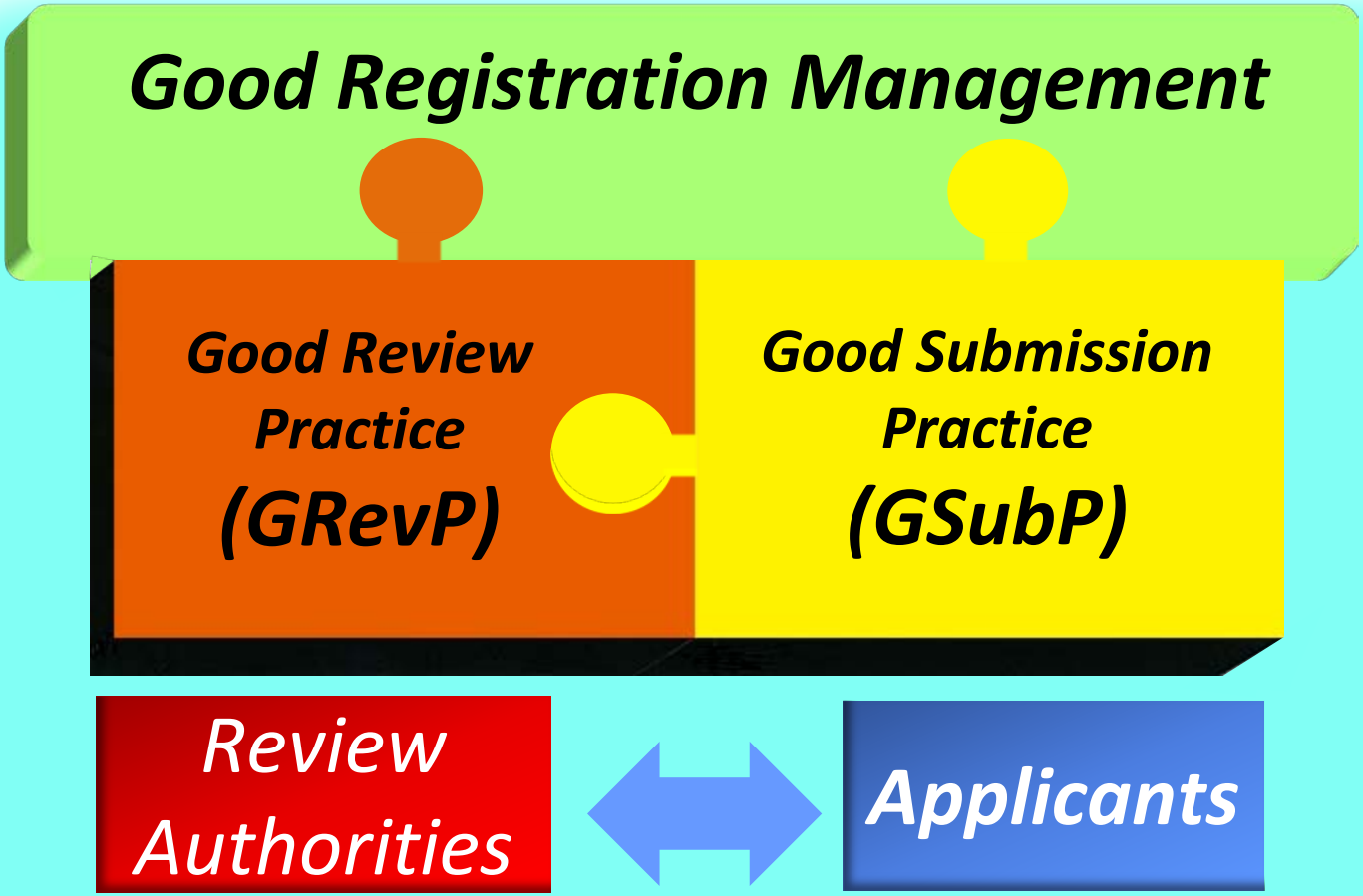
GRM: Mutual Success for Review Authorities and Applicants



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Early access to new medicines!!

APAC GSubP Guideline: Table of Contents

History of GSubP Guideline

Apr. 2015 **APAC GSubP Guideline:** obtained endorsement at the 4th APAC convention meeting.

Apr. 2015 Started revisions of the Guideline (see next slide)

Aug. 2015 Submitted revised GSubP Guideline to APEC RHSC for review

Aug. 2015 – Jan. 2016

Received comments from APEC RHSC/RA-EWG and provided revised version for final confirmation

Apr. 2016 **Revised GSubP Guideline: to be endorsed by APEC RHSC**

RHSC: Regulatory Harmonization Steering Committee
RA-EWG: Regulations and Approvals-Expert Working Group

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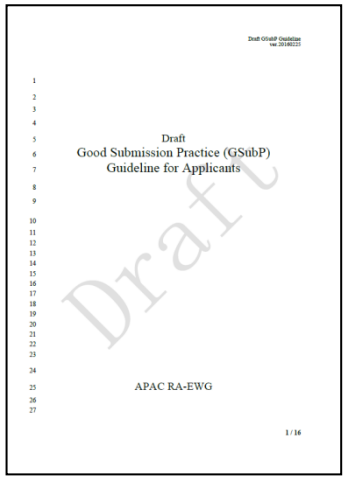
Final draft of GSubP Guideline

Changes from APAC GSubP Guideline

1. Definition of GRevP and GSubP was revised to be consistent with that in GRevP guideline
2. The scope of the guideline was expanded to cover the followings.
   - Beyond APAC region (i.e. eliminated the texts concerning APAC)
   - Other medical products, e.g. medical devices, etc.
   - Small/mid/large sized companies


Draft
Good Submission Practice (GSubP)
Guideline for Applicants
Draft
APAC RA-EWG
1/16

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Dissemination activities of GSubP Guideline

NATIONAL REGULATORY CONFERENCE 2015
(Aug. 4-6, Petaling Jaya, Malaysia)

2015 International Good Submission Practice Workshop on Pharmaceuticals (Sep. 17-18, Taipei)

1st Thailand Pharmaceutical Medicine Conference
(Aug. 25-27, Bangkok)

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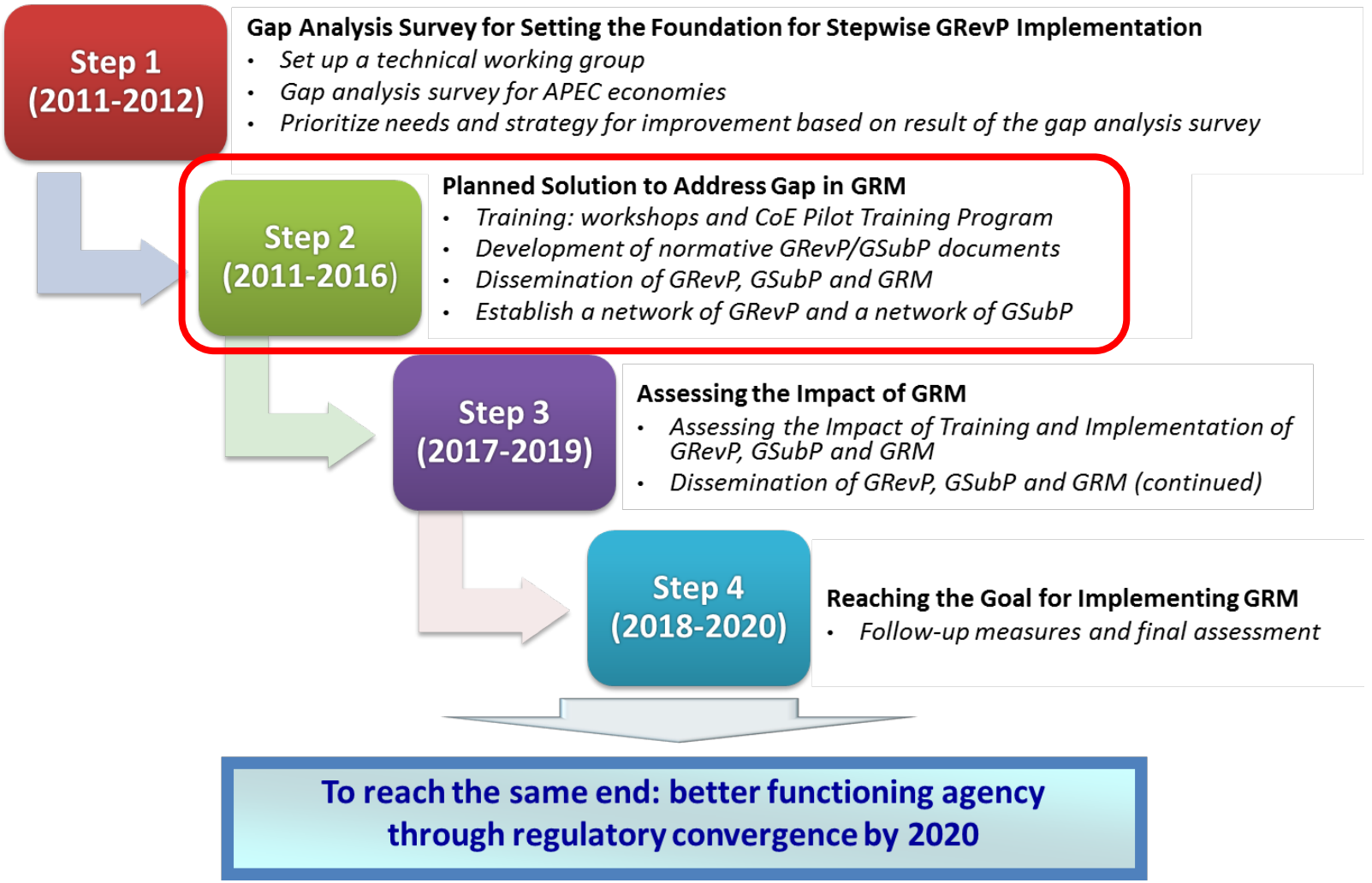
GRM Roadmap for stepwise implementation



GRM: *A concept to promote efficient registration process for medical products by promoting GRevP and GSubP cooperatively.*

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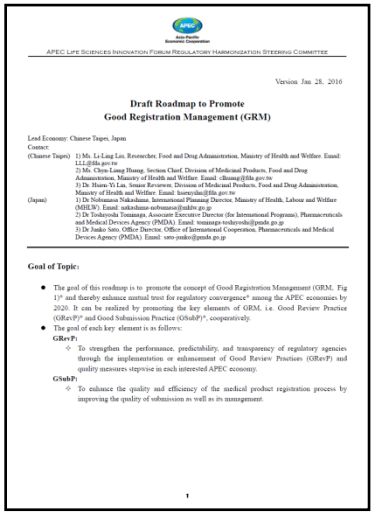
Development of APEC GRM Roadmap document

1. F2F meeting with TFDA/PMDA — Nov. 2015
   - ➢ Discussed outline and structure of GRM Roadmap
2. Working on draft GRM Roadmap document — Dec. 2015 -
   - ➢ Having bi-weekly TC with TFDA/PMDA
3. Submit draft Roadmap to APEC — Feb. 2016
   - ➢ With proposal of CoE pilot training program
4. Obtain endorsement of APEC RHSC!! — Feb 24, 2016



APEC Life Sciences Innovation Forum Regulatory Harmonization Steering Committee

Version Jan 28, 2016

Draft Roadmap to Promote Good Registration Management (GRM)

Lead Economy: Chinese Taipei, Japan

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Goal of Topic:

- The goal of this roadmap is to promote the concept of Good Registration Management (GRM, Fig 1)[a] and thereby enhance mutual trust for regulatory convergence[b] among the APEC economies by 2020. It can be realized by promoting the key elements of GRM, i.e. Good Review Practice (GRevP)[c] and Good Submission Practice (GSubP)[d], cooperatively.
- The goal of each key element is as follows:

GRevP:
- To strengthen the performance, predictability, and transparency of regulatory agencies through the implementation or enhancement of Good Review Practices (GRevP) and quality measures stepwise in each interested APEC economy.

GSubP:
- To enhance the quality and efficiency of the medical product registration process by improving the quality of submission as well as its management.

GRM:
Good Registration Management
RHSC:
Regulatory Harmonization
Steering Committee

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Structure of GRM training

Common Training

1. Basic Concept of GRM
2. Outline of GRevP Guideline
3. Outline of GSubP Guideline

Reviewer Specific GRevP Training

- ✓ To be developed by review authorities

Applicant Specific GSubP Training

- ✓ To be developed by industry
- ✓ Common elements for applicants
- ✓ After CoE Pilot: Can be customized, based on the requirements of application submission in that country/area

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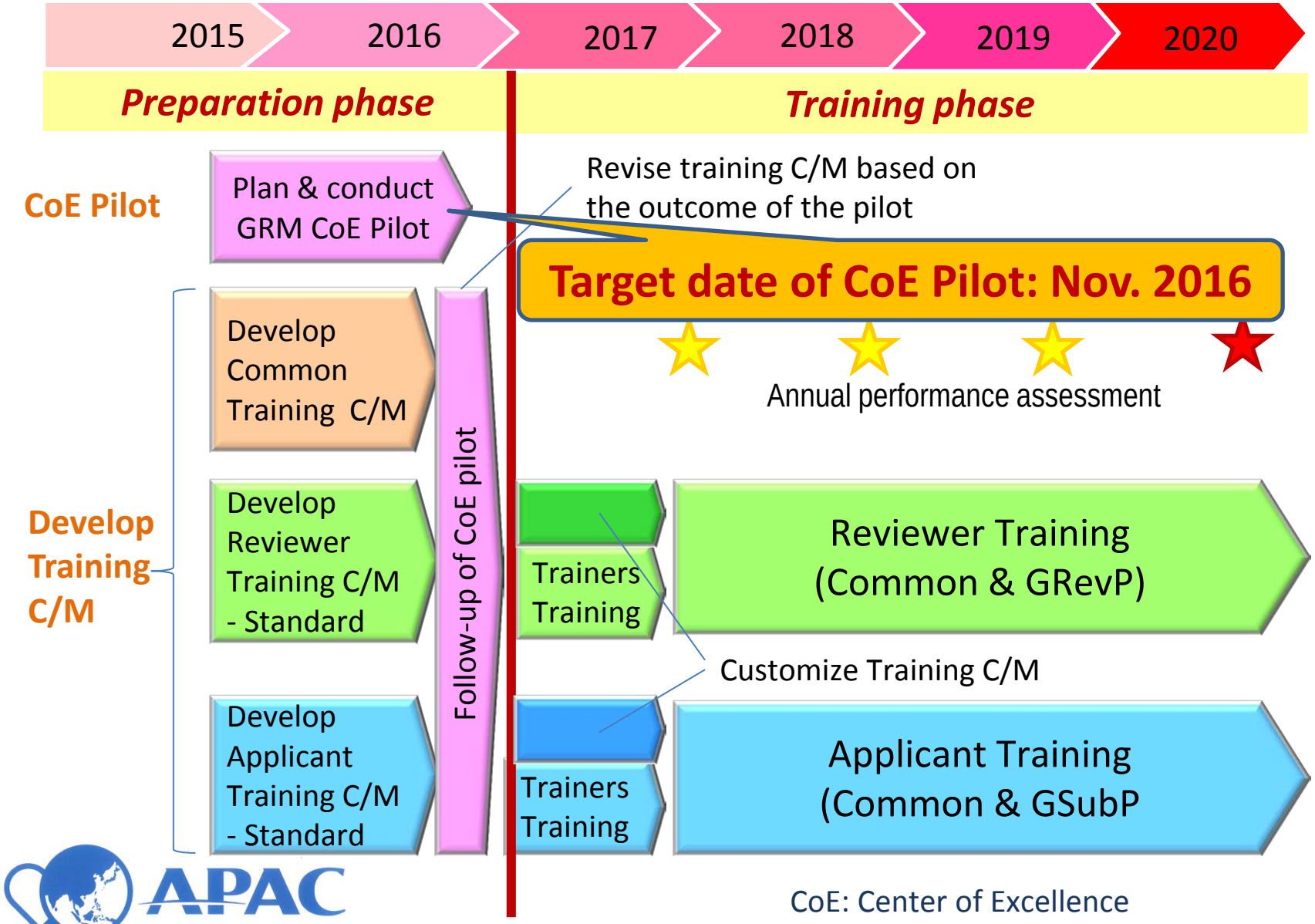
* Good Registration Management (GRevP & GSubP)

Timeline of GRM Training



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

CoE Pilot Workshop Program for applicants -1

Common Training

<Day 1>

Session 1: Basic concept of Good Registration Management

Session 2: Principles of Good Submission

Session 3: Principles of Good Review

Session 4: Case Study: Fundamentals of Communication

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CoE Pilot Workshop Program for applicants -2

Applicant Specific Training

<Day 2>

Session A1: Planning of Application

Session A2: Preparation of application dossier

Session A3: Practice: How to prepare application dossier

<Day 3>

Session A4: Follow-up actions during review period

Session A5: Practice: Case study of how to handle inquiries

Session A6: Panel discussion: How to define the core competency of applicants

Session A7: Guidance for trainer: Rolling out the GRM training program in each economy

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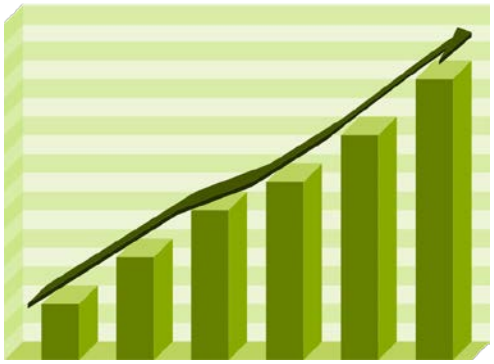
Performance indicators of GSubP

1) Applicants Competency and Training
   - Implementation of technical training programs and soft skills training
   - Number of training certificates issued for qualified trainers
   - Number of training certificates for applicants

2) Quality of Submission (potential evaluation item)
   - Number of major deficiencies/rejection at the filing
   - Number of SOPs and templates available
   - Degree of adherence to each item of the principles of good submission



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

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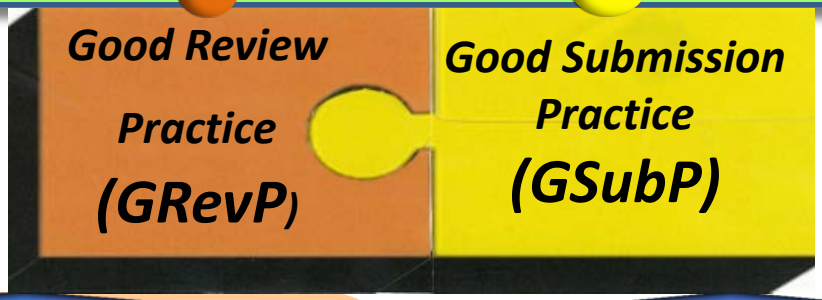
Realize early access to new medicines for peoples in Asia

Enhance efficiency of NDA review

Good Registration Management



Make proposals to support facilitation of GRevP

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

APAC Position Paper

Improve quality of submission and its management

- Reduced number of critical deficiencies
- Decrease of rejections

APAC GSubP Guideline

APAC proposals in the Position Paper (2015)

#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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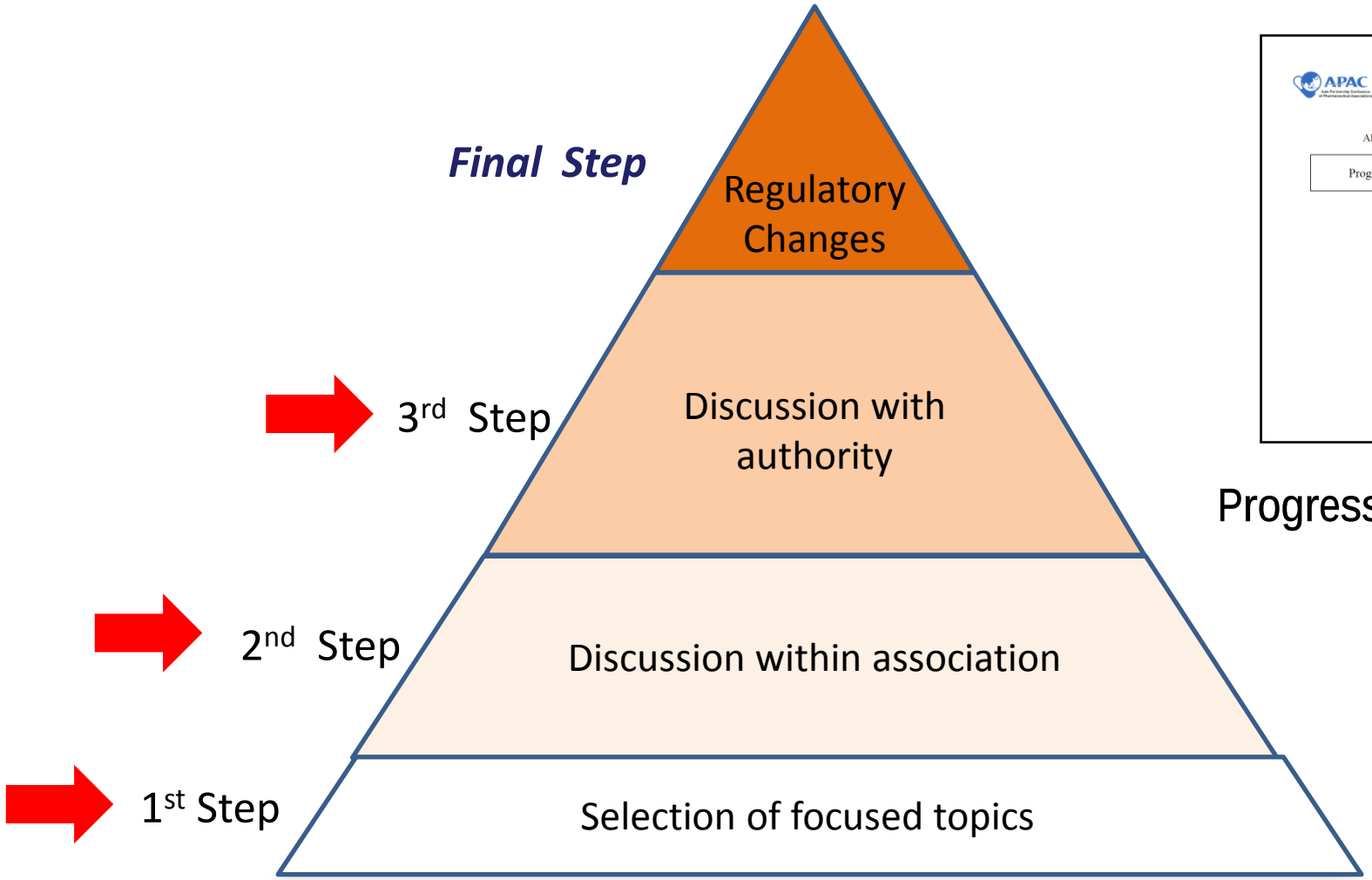
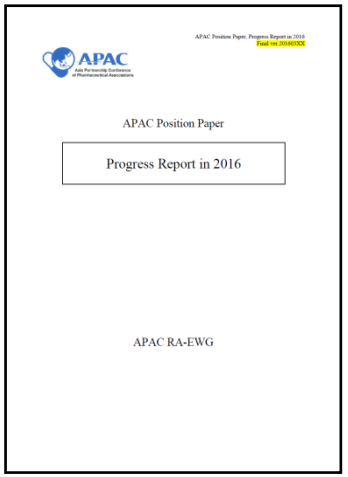
Steps for implementation of Position Paper





Progress Report 2016

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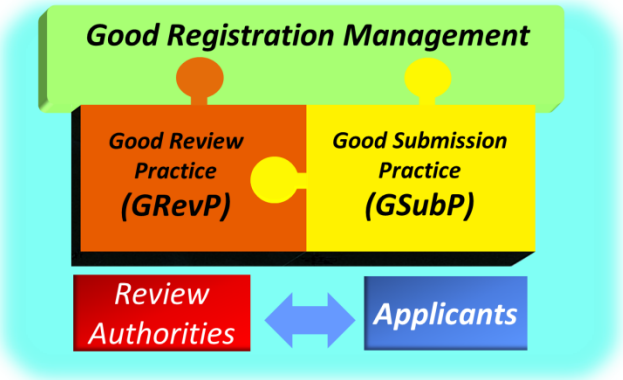
Summary

1. Scope of the GSubP was expanded and it is to be endorsed by APEC RHSC
2. GRM Roadmap document was created in collaboration with Taiwan FDA and PMDA, then endorsed by APEC RHSC
3. GRM CoE pilot training is planned in 2016
4. Task A activity to support facilitation of GRevP is ongoing



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Thank you !