APEC 2020 Roadmap of the Good Registration Management

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Outline

- **Good Registration Management (GRM)**
  - Concept
  - Goal of the GRM roadmap and each key element
- **Specific activities and time frames**
  - Step 1-4 of the GRM roadmap
- **Promote Implementation of GRM through training**
  - Performance indicators of GRevP
  - Plan of a **CoE Pilot Program**
- **Outcome of the LSIF-RHSC, APEC Peru 2016 SOM1**
- **Conclusion**

Concept of the GRM

Promote Efficient Registration Process for Medical Products

Goal of the GRM Roadmap and Each Key Element

- Promote the concept of Good Registration Management (GRM)

Regulatory Harmonization Steering Committee

APEC

Life Sciences Innovation Forum

- Enhance mutual trust for regulatory convergence among the APEC member economies by 2020.

Good Review Practices (GRevP)	Good Submission Practice (GSubP)
To strengthen the **performance**, **predictability**, and **transparency** of regulatory agencies through the implementation or enhancement of GRevP and quality measures stepwise in each interested APEC economy.	To enhance the **quality** and **efficiency** of the medical product registration process by **improving the quality of submission** as well as its management.

Specific Activities and Timeframe of the GRM 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 the gap analysis survey*

Step 2 (2011-2016)

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*

Step 3 (2017-2019)

Assessing the Impact of GRM

- *Assessing the Impact of Training and Implementation of GRevP, GSubP and GRM*
- *Dissemination of GRevP, GSubP and GRM (continued)*

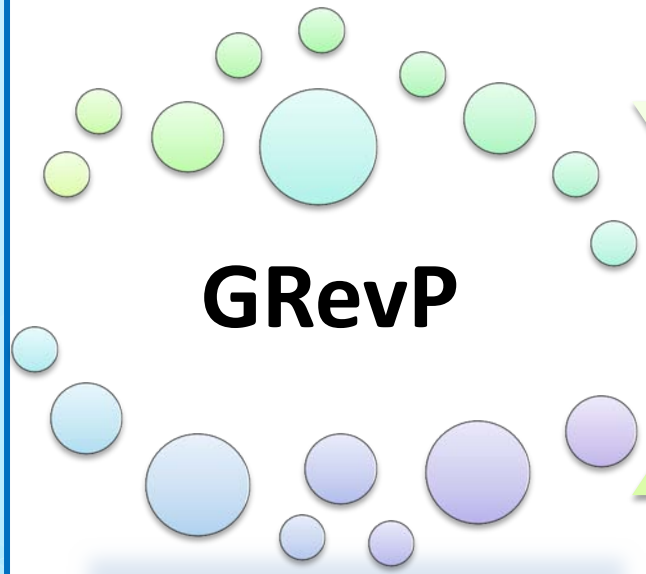
Step 4 (2018-2020)

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

Step 1: Gap Analysis (1)



- Most practices are currently evolving and are applied on an **informal basis**.
- Most agencies have developed **SOPs and guidelines** and **use a variety of training methods**.

✓ **CIRS** conducted a gap analysis survey among 14 APEC regulatory agencies in 2011 and 2012.

Common Approach to Regulatory Review

- ☐ Build **trust and confidence** in each agency's processes
- ☐ Setting the stage for **work sharing**
- ☐ Bringing **consistency and transparency** to the review process

Step 1: Gap Analysis (2)

- **GSubP**: Several articles addressed the issue of quality of application submissions
  - ✓Indicate necessity of promotion of **GSubP by applicants** & **GRevP by regulatory authorities**

- Independent Evaluation of FDA's First Cycle Review Performance –Retrospective Analysis Final Report. January 2006 (by Booz Allen Hamilton Inc.)
- Characterizing Good Review Practices: A Survey Report Among Agencies of APEC Member Economies. TIRS 47(6) 678-683, 2013
- Building Quality into Regulatory Activities: What does it mean? June 2006 (by CMR International

Step 2: Planned Solution to Address Gap in GRM (1)

(1) Training: Workshops and CoE Training Programs

- **GRevP training workshops** in Chinese Taipei (2011-2012)
- **GRM CoE Pilot Training Program** including GRevP and GSubP is being planned for late 2016 in Chinese Taipei.

(2) Develop Normative GRevP/GSubP Documents

- **"Good review practices: guidelines for national and regional regulatory authorities"** was published in 2015.
- **The draft of "Good submission practice (GSubP): guideline for applicants"** was developed by APAC in 2015 and is under review by APEC RHSC and WHO.

Step 2: Planned Solution to Address Gap in GRM (2)

(3) Dissemination of GRevP, GSubP and GRM

- Presentations in national/international conferences and workshops

(4) Establish Networks of GRevP and GSubP

- The networks may include experts and competent organizations.
- Use the workspace on RHSC Website

Step 3: Assessing the Impact of GRM

Assessing the Impact of Training and Implementation

- Initiate the **training of trainers** for reviewers and applicants.
- **Extend the CoE training program** to full-scale, continue assessing the outcomes of training, and evaluate the impact of implementation.

Dissemination of GRevP, GSubP and GRM (continued)

Continue dissemination activity of through national/international conferences and workshops.

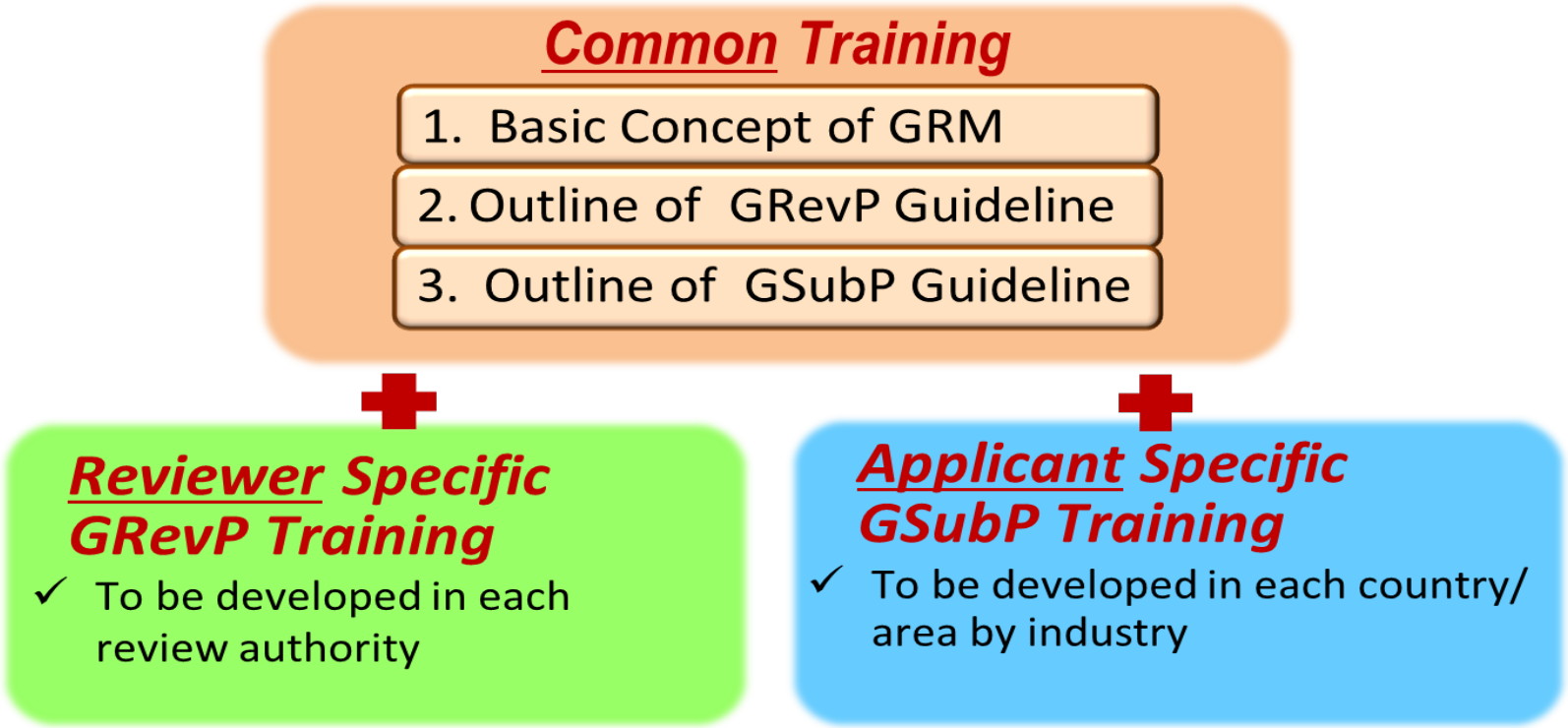
Step 4: Reaching the Goal for Implementing GRM

■ Follow-up Measures and Final Assessment

- **Take follow-up measures** according to the outcome of annual assessment conducted in Step 3.
- **Conduct final assessment** and prepare a final assessment report for the outcomes of the GRM roadmap.

Promote Implementation of GRM through Training

Proposed Structure of GRM Training



Performance Indicators of GRevP

1. Roadmap Outputs

Checklist of Deliverables

1. Good review practices: guidelines for national and regional regulatory authorities. WHO Technical Report Series, No. 992, 2015, Annex 9
2. Materials and reports from “2011 APEC Good Review Practice Workshop on Medical Products” and “2012 APEC Advanced Workshop of Good Review Practice on Medical Products”
3. Training curriculum and materials or e-learning targeting on training of regulators
4. Related documents based on each step of the roadmap, including gap analysis survey reports, final assessment survey report, and progress reports
5. Final assessment report on the impact of this roadmap in promoting GRevP

Performance Indicators of GRevP

2. Measurable Outcomes

1 *Reviewer 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 regulators

2 *Use of Templates and Procedures*

- Number of SOPs and templates available
- Degree of adherence required for following SOP

3 *Transparency, Consistency, Predictability and Timeliness*

- Number/ Type of information accessible by public online
- Involvement of stakeholders
- Establish checkpoints and set target timelines for review, and determine how many reviews have met these targets
- Adoption of peer review
- Establishment of a quality system

Plan of a CoE Pilot Program (1)

Topic of the Event

- APEC RHSC Center of Excellence Pilot Workshop “Good Registration Management” *(tentative)*

Expected dates of the Event

- November 15-17, 2016 *(tentative)*

Focus

- Developing the knowledge, skills and competencies for effective registration of medical products, that is GRevPs and GSubPs.
- This will include scientific, technical and regulatory aspects as well as essential communication, information management and critical thinking skills.
- This will be accomplished by building a solid base of knowledge and developing competencies through case based learning.

Plan of a CoE Pilot Program (2)

Target audience

- **Senior regulators** with at least 3 years of hands-on experience in the management of regulatory reviews
- **Industry managers** with at least 3 years of hands-on experience in the management of regulatory submissions

Structure

- **On-line** and **self-paced learning** to develop knowledge base in advance of in-person training
- **In person training**: 3 days with plenary sessions for all attendees and parallel sessions for regulators and industry based professionals with lectures, group discussions and applied case studies

Plan of a CoE Pilot Program (3)

- **Partners:**

RHSC Working Groups	CoE hosting institution	Advisory Committee
• **Contents group** responsible for the key contents of the workshop program • **Logistics group** responsible for logistics and administrative items	• **Regulatory Affairs Professionals Society (RAPS)** responsible for inviting faculty, developing training materials and hosting the pilot program	• 10-15 GRevP and GSubP subject matter experts to assist in program development, review and recommendation of additional faculty

- **Funding for the pilot:** CoE, TFDA, industry, and other potential sources

Plan of a CoE Pilot Program (4)

Curriculum: Common Training

Day 1

Session 1	Session 2	Session 3	Session 4
• Basic concept of Good Registration Management	• Principles of Good Submission	• Principles of Good Review	• Case Study: Fundamentals of Communication

Venue: Grand Hotel Taipei

Plan of a CoE Pilot Program (5)

Curriculum: Specific Training for Applicant

Day 2

Session A1	Session A2	Session A3
• Planning of Application	• Preparation of application dossier	• Practice: How to prepare application dossier

Day 3

Session A4	Session A5	Session A6	Session A7
• Follow-up actions during review period	• Practice: Case study of how to handle inquiries	• Panel discussion: How to define the core competency of applicants	• Guidance for trainer: Rolling out the GRM training program in each economy

Plan of a CoE Pilot Program (6)

Curriculum: Specific Training for Reviewer

Day 2

Session R1	Session R2	Session R3
• Fundamentals of communication: Case study of inquiries and answers	• Managing the review	• Quality system for reviewers

Day 3

Session R4	Session R5	Session R6	Session R7
• Reviewer expertise, competencies, and training	• Critical thinking	• Key elements and strategies of a good review	• Guidance for trainer: Rolling out the GRM training program in each economy

Outcome of the LSIF-RHSC

Decisions

- GRevP and GSubP have been merged into one Roadmap – Good Registration Management (GRM).
- **The Roadmap was endorsed.**
- **Japan was endorsed as a GRM Roadmap Co-Champion.**
- A GRM CoE Pilot in November 2016 was proposed and endorsed by RHSC. RAPS will serve as the CoE.

Action Item

- **JPMA to circulate a revised Good Submission Guideline** as soon as possible for RHSC comment by the end of March 2016.

Conclusion

Good Registration Management (GRM) represents a novel concept to promote efficient registration process and enhance mutual trust for regulatory convergence among the APEC member economies.

The 2020 Roadmap to Promote GRM was recently endorsed by APEC RHSC.

- **Future focus will be on training and assessment of the impact of GRM in promoting regulatory convergence.**

Training programs will be developed through the Center of Excellence (CoE)

- **First GRM CoE Pilot will be held in Nov. 2016 in Taipei**

Thank You for Your Attention