Background Review of GRevP Project - Findings from Basic Workshop

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Welcome to Taipei for 2012 APEC GRP Workshop

TAIWAN
Touch Your Heart








Our Mission

- **Objective: to forge a common understanding of Good Review Practices (GRevPs) and Quality Systems, why they are important, and how they may be applied within agencies**
- **While concepts not new, important milestone in advancing discipline of GRevPs**
- **Format:**
  - **Framed discussions**
  - **Interactive**
  - **Case studies**
- **Builds upon 2011 basic workshop**

The Context

"Best Regulatory Practice" project proposed by Chinese Taipei

- ***"Best Regulatory Practice of Medical Products for Trade Facilitation"***
  - a strategic approach for Good Review Practice
- **Co-sponsoring APEC Economies:**
  - Canada, China, Indonesia, Korea, Malaysia, Mexico, Peru, Philippine, Thailand and United States
- **Approved and funded by APEC, December 2010**

Key Objectives

- To ***reduce regulatory burden*** and ***achieve timely market*** access of medical products through the adoption of best regulatory practice
- To ***establish mutual confidence*** in the assessment reports of regulatory authorities within the APEC region
- To ***provide a platform*** for regulatory dialogue

Three components of the project

- ***A survey*** to examine the disparities of Good Review Practice and approaches to scientific assessments among APEC economies
- A series of 3 to 5-day ***Workshops*** covering both pharmaceuticals and medical devices (Chinese Taipei, 2011 / 2012)
- A ***pilot study*** on use of available regulatory review reports from other participating agencies by voluntary basis

Regulators on Critical Path

- **The extent to which regulatory authorities fulfill their mandate in a timely, effective and consistent manner can have significant impact on access to medicines, public health, product development costs and promoting conducive environment for research and innovation**
- ***At issue:* the contribution of Good Review Practices (GRevPs) to a well-functioning regulatory review system and to inter-agency cooperation**

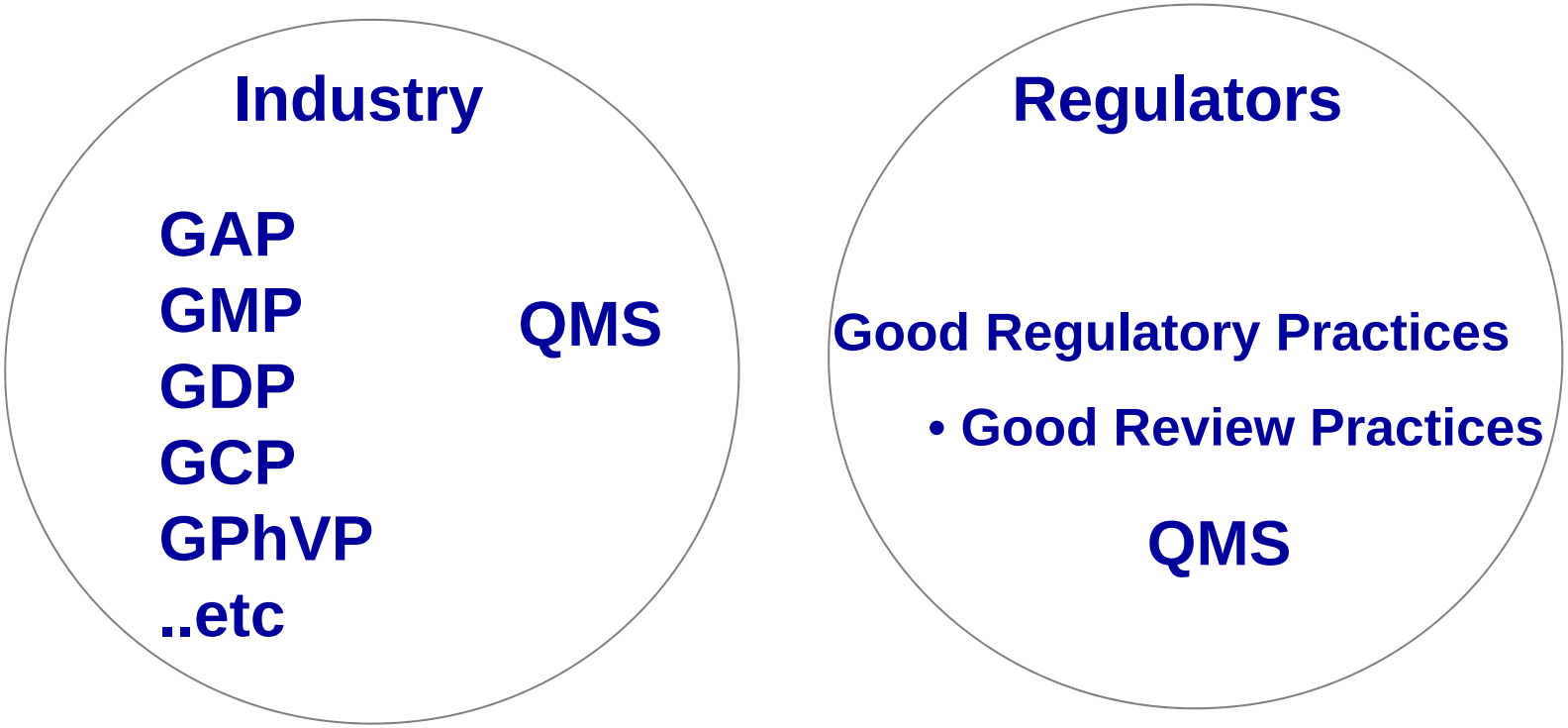
The case for GRevPs

- Review highly complex undertaking
- Forms scientific basis for regulatory decisions, consequences of which highly significant
- Can’t clone experienced reviewers
- Essential to promoting consistency, transparency and performance

GRevPs not a panacea, but..

- **Good Review Practices can't and perhaps shouldn't take the 'art' out of review, but should provide those involved in review and decision-making process the best possible support and tools for ensuring consistent, science-based assessments that comply with legal requirements**

GxP and QMS



Common Objectives: Consistent, high quality product

Good Review Guiding Principles

- A good product review is an independent, objective, scientific and timely analysis of information relevant to a marketing application
- Considers context (proposed conditions of use) and regulatory framework within which assessments and decisions made
- Documents in clear and consistent manner all evidence and considerations taken into account in reaching conclusions, recommendations and decisions

Common Elements

- **While no single definition of GRevP exists, common elements include:**
  - **Principles, procedures and templates related to the review process, including its management, peer review, use of internal/external advisory and interactions with sponsors**
  - **Orientation and training for staff and management linked to defined competencies**
  - **Information repositories**

Part of continual improvement process

- Conducting internal quality audit
- Self-assessments
- Analyses of feedback from stakeholders
- Post-approval analysis with other authorities and industry
- Management reviews

→ using the results to take corrective action or introduce improvements to the review process and decision-making

Role of GRevP in promoting trust and confidence

- **The belief:**

  Implementation of good review practices, combined with adoption of common, science based standards and guidelines that define regulatory expectations for establishing the safety, efficacy and quality of medicinal products, are essential in building trust and confidence in regulatory systems

Role of GRevP in promoting trust and confidence (2)

- GRevPs should then be important not only within domestic context but also in building trust and confidence among regulatory authorities which in turn essential for inter-agency exchange and optimal use of regulatory information
- GRevPs help ensure that review reports are well structured, comprehensive, clear and consistent - key considerations in potential use by other authorities
- Should also influence selection of partners for joint reviews or other forms of 'real time' collaboration and dialogue

Presumptions in looking ahead

- **The contribution of GRevPs to interagency cooperation has not been fully realized**
- **The evolution and implementation of GRevPs within agencies coupled with the increasing need to leverage one another's resources and work will become increasingly important**

Further Considerations

- **Doesn't mean that decisions of different agencies will be the same: need to distinguish assessment of quality, safety and efficacy from broader benefit-risk considerations specific to a particular country and health care systems**
- **Also doesn't mean that one size or approach to GRP fits all agencies: different approaches and best practices more likely**
- **Equivalence rather than harmonization**
- **EU experience: glimpse of things to come?**

2011 APEC Basic GRevP Workshop (Oct. 12-14, 2011, Taipei)

2011 APEC GRevP Workshop on Medical Products

Day	Activities
Oct. 11 (day 0)	Registration and Pre-meetings among moderators, speakers, rapporteurs and mentors
Oct. 12 (day 1)	•Session A--The Basics •Session B--The Details (Concurrent Drug and Device Sessions)
Oct. 13 (day 2)	•Session B--The Details (Concurrent Drug and Device Sessions continued) •Session C--Metrics
Oct. 14 (day 3)	•Session D--Information Resources (Concurrent Sessions) •Session E--Transparency
Oct. 15 (day 4)	•Session F--Good Review Practices on Medical Products •Session G--Industry Responses •Session H--Panel Discussion

Basic GRevP Workshop Overview

- **The Basics**
  - Definition - scope and key elements
- **The Details**
  - Orientation and training
  - Procedures and templates
- **Metrics**
  - Measurement, Stakeholder Feedback
- **Transparency and Information Sharing**
  - Peer review and external experts
  - Sharing between agencies, between agency and companies, between agency and public

Orientation and training

Templates / SOP

- Useful or not?
- How to do they contribute to quality control?
- How much details?
- Flexibility?
- Frequency of updating?

Metrics

- ***Metrics*** can be used to set targets, monitor, and improve elements of a quality review
- ***Timeliness:*** can be measured internally or externally; in aggregate or in detail; is affected by quality
- ***"Quality":*** Encompasses many metrics; can be measured internally or externally
- ***Stakeholder feedback*** is an important component of continuous quality management

Metrics

- Conducting internal quality audit - Self-assessments
- Analyses of feedback from stakeholders
- Post-approval analysis with other authorities and industry
- Management reviews
- Using the results to take corrective action or introduce improvements to the review process

Peer Review

- **Peer review is an additional evaluation of an original assessment that is carried out by an independent person or committee. Peer review can occur either during assessment of a dossier or at the time of sign-off**
  - Internal
  - External

External Experts

- **Consultants**
  - A professional who provides expert advice in a particular domain or area of expertise
- **Contractors**
  - Conformity assessment body (e.g Center for Drug Evaluation, third party review…)
- **Advisory Committees: Committed members, regular meeting , recommendations may affect regulatory decision**

Conflict Interests?

Next Steps after Basic GRevP Workshop

- **Revise roadmaps on GRevPs**
- **Analyze findings from surveys**
- **Develop a best practice document on GRevPs**
  - Definition
  - Elements
  - Suggested approaches to implement or enhance GRevPs
  - Metrices and assessment
- **Establish annual curriculum of GRevPs**
- **Establish pilot study and possible framework on the exchange and use of regulatory information**

2012 APEC Advanced GRevP Workshop November 6-8, 2012, Taipei

- **Venue: The Great Roots Forestry SPA Resort, Taipei**
- **5 topic areas to be discussed:**
  - Review of 2011 Workshop
  - Quality System & Gap Analysis
  - Key Elements & Strategies of a Good Review
  - Critical Thinking & Decision Making: Drugs & Devices
  - Transparency and interactions

Culture Night

Thank You

謝謝

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Roadmap to Promote Good Review Practice (GRevP) for Medical Products

Goals

- To ***implement Good Review Practices in each interested APEC economy*** in order to ensure better review quality of medical products and to reach a better functioning agency by 2020
- To ***enhance mutual trust*** for regulatory convergence between economies

Draft of 2020 Roadmap for GRevP on Medical Products

Step 1 (2011-2012)

Gap Analysis Survey for Setting the Foundation for Stepwise GRevP Implementation

Step 2 (2011-2014)

Advancing the Process, including Training

1. Develop GRevP document
2. Set up quality management system (QMS)
3. Set up strategic program through training workshops

Step 3 (2012-2015)

Assessing the Impact of GRevP Training and Regulatory Information Sharing

Step 4 (2015 -2020)

Reaching the Goal for Achieving Common Regulatory Elements

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 strategies for improvement based on the result of the gap analysis survey

Step 2 (2011-2014)

- ***Advancing the Process*, Including Training**
  - Develop Normative GRevP document
  - Set up quality management system (QMS) within interested economies
  - Set up strategic program through training workshops

Step 3 (2012-2015)

- ***Assessing the Impact*** **of GRevP Training and Regulatory Information Sharing**
  - The effect of the trainings should be evaluated for the status of implementing relevant guidelines. Present the result in an open stakeholder conference and invite comments from regulatory agency, academia, industries and consumers

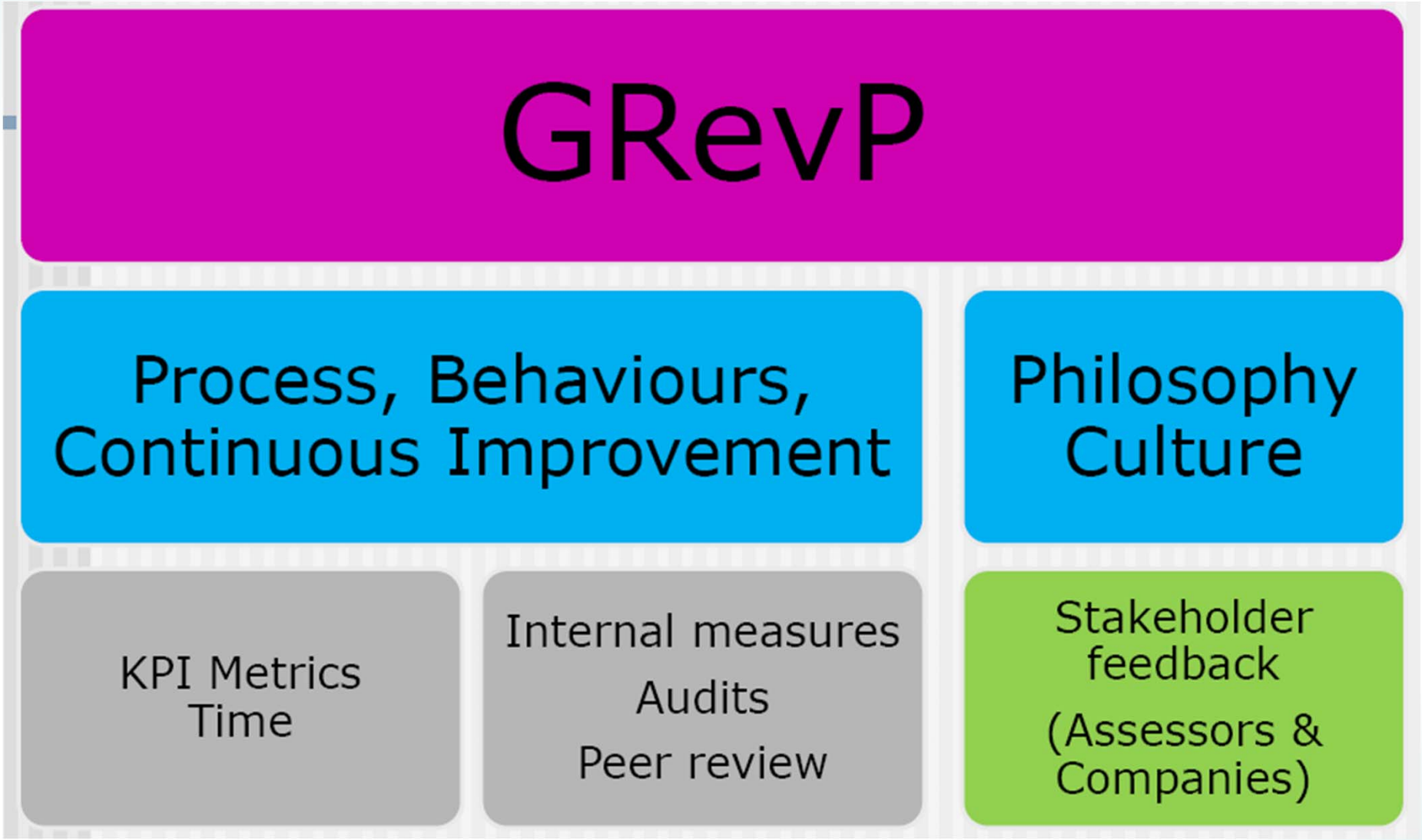
Step 4 (2015-2020)

- ***Reaching the Goal*** **for Achieving Common Regulatory Elements**
  - Evaluate implementation of GRevP
  - Recommendations for further regulatory harmonization

Performance Indicators

- Readiness assessment
- Training
- Establishment of database for review templates and reports
- GRevP document on medical products
- Progress report according to the goal of GRevP roadmap

Observations



- **GRP: Definition of Good Review Practices are *review standards* (such as standard operating procedures and templates) and related *initiatives* (such as reviewer manuals and training programs) designed to ensure the *timeliness*, *predictability*, *consistency* and *high quality* of reviews and review reports**