GCG - Fukuoka 2012

Agenda Item 13

Implementation of Good Review Practices

GRP
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Implementation of Good Review Practice - Project Update

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Global Cooperation Group
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Outlines

- Introduction
- APEC Priority Work Areas
- APEC GRevP Workshops
- Next Steps

APEC LSIF Vision of Regulatory Convergence for Medical Products by 2020

Regulatory Convergence

Roadmaps

Proposals for Projects

Priority Work Areas

Strategic Framework

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FDA

APEC Priority Work Areas

Basic research → Pre-clinical → Clinical Trials → Product Launch → Post-market surveillance

MRCTs
GCP Inspection

Global Drug Integrity and Supply Chain

Good Review Practices
Biosimilars

PMS
-Vigilance
- Inspection/Auditing

FDA

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

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GRevP Project Brief

(Chinese Taipei project)

- Best Regulatory Practice of Medical Products (pharmaceuticals and medical devices), A strategic approach for Good Review Practice, GRevP

- Canada, China, Indonesia, Korea, Malaysia, Mexico, Peru, Philippine, Thailand and United States

Approved and funded by APEC

- December 2010

GRevP Project Brief

(Chinese Taipei project)

- A survey for Gap Analysis
- A Feasibility Study for Exchange for Regulatory Information
- Good Review Practice Workshops
  - Basic: 2011. 10. 12-14 (Taipei)
  - Advanced: 2012. 11. 6-8 (Taipei)

GRevP Project –Survey for Gap Analysis

- Coordinated by Chinese Taipei, collaborated with CIRS
- Sent survey to APEC economics for the current status of Good Review Practice on Medical Products in 2011
- Draft report completed by CIRS in Feb., 2012

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Summary of Survey

- A consistently defined GRevP code has been implemented formally/informally by most NRAs
- Most NRAs would improve their GRevP through natural evolution and training
- Quality measures are being implemented to ensure consistency and improve efficiency and transparency
- Most NRAs have implemented audit/feedback mechanisms to ensure adherence to quality measures
- Most NRAs believe that quality measures will increase confidence in their system
- Not all NRAs use Assessment Templates for NAS reviews

NRA: National Regulatory Authority
9 NAS: New Active Substance

Summary of Survey (cont.)

- Target times help guide activities but electronic tracking systems need to improve to maximize value of tracking
- Many NRAs have implemented tools (application, processes, formal/informal meetings, meeting dates, SBAs) to enhance industry interactions but engagement opportunities could be improved
- Most NRAs use several ways to train reviewers: all felt the need for GRevP training by APEC especially on:
  --Using Assessment Frameworks
  --Good Review Practices
  --Good Review Management practices

10 SBA: Summary basis for approval

Survey for Regional Information Exchange

- 10 NRAs willing to share their NDA assessment templates with CIRS
- Most NRAs consider it beneficial for better quality and efficiency in review
- Some minor concerns need to be solved before exchange like confidentiality issues
- A few NRAs showed interest in pilot study

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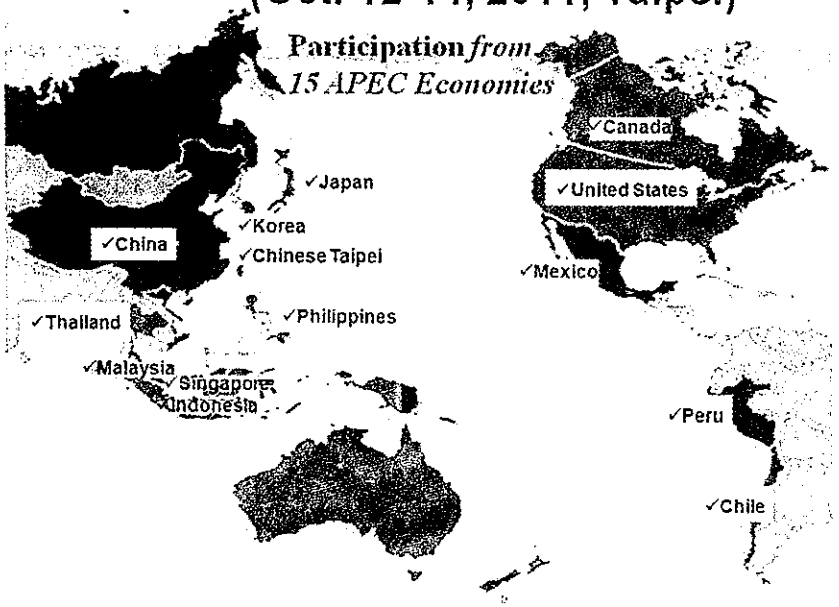
2011 APEC Basic GRevP Workshop (Oct. 12-14, 2011, Taipei)



Overview of 2011 GRP Workshop

The Basic	• Common understanding of the scope and key elements in GRevPs • Tools
The Details	• Knowledge and Skills (reviewers' competence) • Procedures and Templates
Metrics	• Measurements on Review Quality • Stakeholder Feedback
Information Resources	• Peer review • External experts
Transparency & Information Sharing	• Sharing between agencies, agency to companies and to public

Consensus from 2011 APEC Basic GRevP Workshops

- Competence building of reviewers
- Template and procedure for review standard
- Need to establish measurement for review quality
- The role of industry and stakeholders
- The information and experience sharing among agencies

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The Scope of GRevP (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

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GRevP: The Working Definitions

A code about the standardization of quality control and documentation of the review procedures, general principles of review, and training that aims to ensure the efficiency, predictability, consistency, transparency and high quality of a science-based assessment of medical products.

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2012 Advanced GRevP Workshop Overview (draft)-1

- Definition, Common Elements of GRevP
- Practice Good Review by Case Studies
- Develop Framework Documents – Template, SOP
- Metrics – internal and external measurements for review quality
- Decision Making – critical thinking and balance between risk and benefit

2012 Advanced GRevP Workshop Overview (draft)-2

GRevP Survey Report – Gap Analysis, and Prioritize the Needs

Strategies and Methodologies for Improvement

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Next Steps

- Complete framework documents on GRevPs
  - –Definition
  - –Elements
  - –Approaches to implement or enhance GRevP
  - –Metrics and assessment
- Establish Curriculum of GRevP
- Establish possible framework and pilot study on the exchange and use of regulatory information

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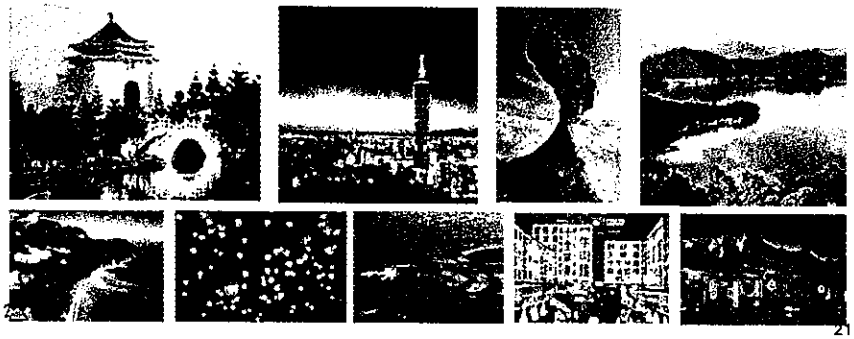
Welcome to Taipei for
APEC Advanced GRevP Workshop
in November 6-8, 2012



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