財團法人醫藥品查驗中心
Center for Drug Evaluation

Regulatory Science,
Service for Life

Summary of Advanced Workshop of Good Review Practice on Medical Products

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Participation *(by Nationality-19)*

- ✓ Australia
- ✓ Belgium
- ✓ Canada
- ✓ China
- ✓ Chile
- ✓ Indonesia
- ✓ Italy
- ✓ Japan
- ✓ Malaysia
- ✓ Mexico
- ✓ Netherlands
- ✓ Peru
- ✓ Papua New Guinea
- ✓ ROC (Taiwan)
- ✓ Saudi Arabia
- ✓ Singapore
- ✓ Thailand
- ✓ United Kingdom
- ✓ United States

2012 APEC 亞太經合會藥品及醫療器材優良審查規範進階研討會
Advanced Workshop of Good Review Practice on Medical Products

November 6-8, 2012 in Taipei

Asia-Pacific Economic Cooperation

Food and Drug Administration Chinese Taipei

Center for Drug Evaluation Chinese Taipei

2012 APEC Advanced GRevP Workshop

✓ Objective

- to forge a common understanding of Good Review Practices (GRevPs), why they are important, and how they may be applied within agencies

✓ Format

- Framed discussions
- Interactive
- Case studies

Workshop Overview

Session A. Review of Findings from Basic GReVP

Session B. Quality System for Reviewers

Session C. Key Elements & Strategies of a Good Review

Session D. Critical Thinking & Decision Making

Session F. Transparency and Interactions

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Session A: Review of Findings from Basic GReVP

✓ **Background review from GReVP project**

What's GReVP project

→ To *reduce regulatory burden* and *achieve timely market* access of medical products

→ To *establish mutual confidence* in the assessment reports of regulatory authorities within the APEC region

→ To *provide a platform* for regulatory dialogue

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

Session B: Quality System for Reviewers

- ✓ **Quality System is defined as an organizational approach to produce, maintain, ensure, and improve the fitness-for-use of a product or service.**
- ✓ **Produce, Maintain, Ensure, and Improve**

  Do what you say

  Say what you do

  Prove it

  Improve it

Session B: Quality System for Reviewers

- ✓ Experience sharing from various agencies

  SOPs is a large part of the GRP Project.

SOPs provide instructions for reviewers on how to prepare regulatory review reports

Allow for justifiable variation in following procedures

  Review template

  Training of reviewers

  Auditing

- ✓ A survey from APEC member economies agencies

Session B: Quality System for Reviewers

- Breakout session A/B/C/D

- **Process steps in PDCA**

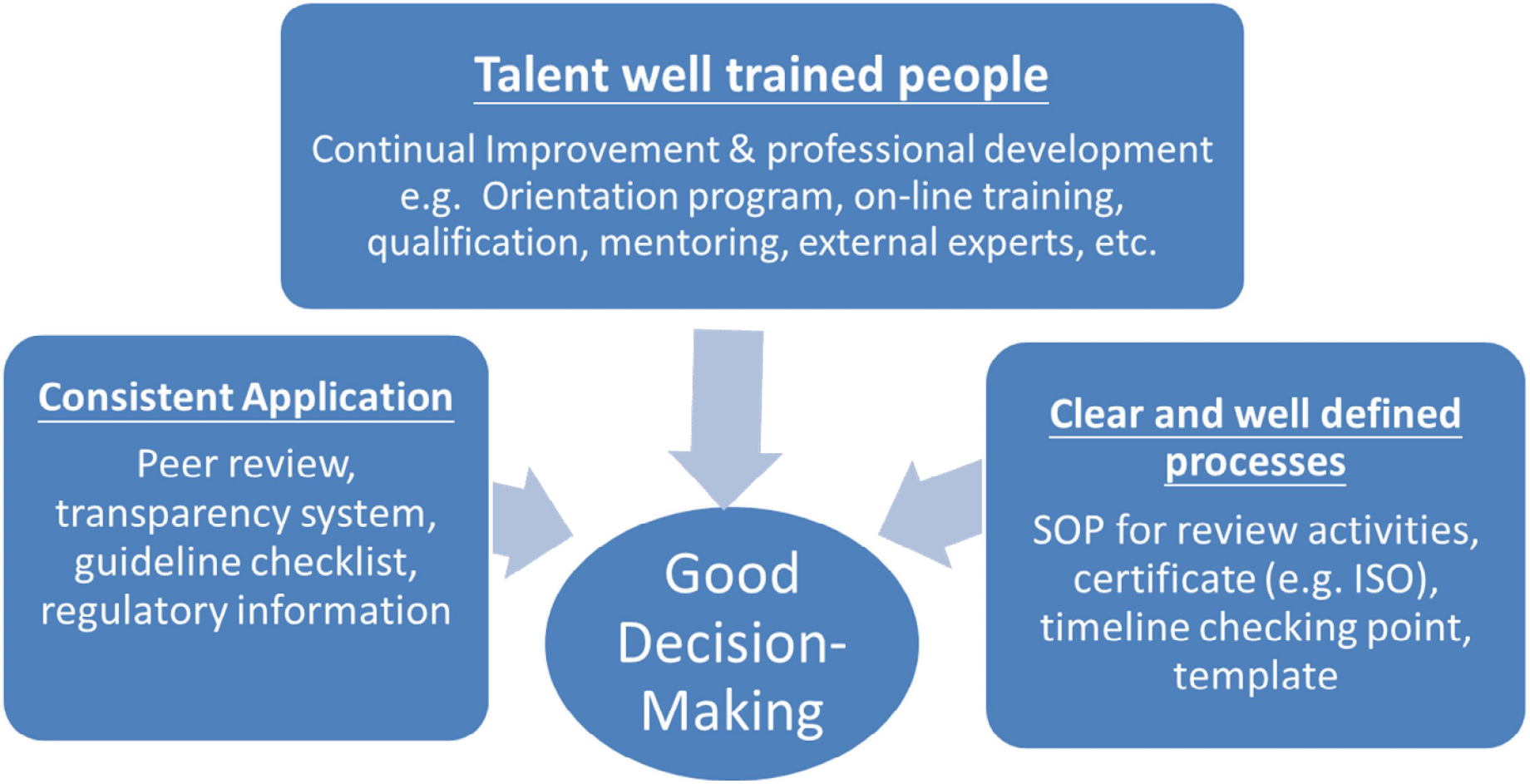
  Plan→ plan what to do

  Do→ implementing the plan

  Check and Act→ determine whether the plan worked, if not should develop a alternative and precise measurement

***Ranking the level of effort & impact**
*** What is your priority!?**

Session B: Quality System for Reviewers



And accelerate review time!

Session C: Key Elements and Strategies of a Good Review

✓ Objectives

Understand the basic aspects of a good review.

Share experiences on different strategies to produce good reviews.

Consider which elements and strategies need to be developed / improved in your own economy.

✓ Methods

Experience sharing by FDA, FDAAA and Healthy Canada.

Breakout session A/B/C

Session C: Key Elements and Strategies of a Good Review

- **Pre-filing strategies** is more than just meeting preparation
  - a. Review tools (templates, guideline, paradigms, electronic)
  - b. Appropriate skills
  - c. Don't re-invent the Wheel (using database for consistency)
  - d. Reviewer's attitude ←→ expectation from sponsor

Session C: Key Elements and Strategies of a Good Review

- Good review initiation strategies will facilitate the review process

  Screening/validation, early identification of serous deficiencies, kick-off /filing meetings, consultation needs (internal/external, AC), pre-submission sponsor meeting

Session C: Key Elements and Strategies of a Good Review

- **Post-initial review strategies** ensure a complete and thorough review
  - Peer review, team meetings, internal panel review, external panel review, mixtures.
  - Establish guidelines about good implement of these strategies and traninig with case studies.

  →Increase the quality and transparency of review process.

Session D: Critical Thinking and Decision Making

✓ Objectives

To stimulate and discuss the key elements of critical thinking and decision-making in review, Focusing on issue in safety, efficacy, and the need for risk management.

✓ Method

- Parallel session in drug and medical device
- Case study of anticancer drug
- Case study of CMC change

Session D: Critical Thinking and Decision Making

- **Approval of New Drugs**

1- Systemic approach to assessment of data using review templates and SOP. Take risk-based approach, due to limit of resources.

2 - Judge what is the best for public health. Evaluation of risk and benefit should be done on a population basis.

- Realize that some persons will not have response to this drug and have adverse events.

Session D: Critical Thinking and Decision Making

- **Case Study of Anticancer Drug**

1. **Where there is "unmet medical need", no approved drug exists, and the incidence of the disease is low, we take flexible approach.**
2. **Sponsor may claim sustained benefit but be cautious to look at missing data. That's one way of critical thinking.**
3. **Examine consistency of effect in relevant subgroup analysis.**

Session D: Critical Thinking and Decision Making

- **Case of CMC change from Phase III→NDA**

1. **The existing guidelines on how to assess and document the equivalence of product quality and performance for a CMC change post-approval can be applied to pre-approval; and**
2. **It would be precedent for regulators to consider improving the existing guidelines by cooperating the science, risk-based, quality-by-design (QbD), lifecycle approaches outlined in the ICH Q8/9/10/11.**

Session D: Critical Thinking and Decision Making

Medical Devise

- Key Step→ identify questions and to define if a question is critical or non-critical.
- Not all economies have a medical device regulatory section.
- The differences between the pharmaceutical measures and medical devices measures shall be understood and well-noticed by the authorities/review parties, law-makers, and the public.

Session E: Transparency and Interactions

✓ Objectives

To be transparency in review process, sharing review situation and consider the interaction with public, industry, stakeholders, and regulatory agencies

✓ Methods

Experience sharing from EMA, Japan, Taiwan CDE, and Thailand FDA

Session E: Transparency and Interactions

- **With Public and External Stakeholder**

- Published information in regulatory website

Ex. public assessment report, public guideline consultation, data sharing

- Involvement of Stakeholder/public

Scientific advice, patients' involvement, open workshop, advisory committee

- Data protection

SOP for data storing/sharing, protecting personal data, confidential information, quality standard, rules of engagement

Session E: Transparency and Interactions

- **Interaction between Regulatory Authorities**

- EMA experience by Francesca Cerreta

- Use of review reports from other agencies

- a recent example (Consortium Generics Initiative), experience by Health Canada

- ASEAN Harmonization on Pharmaceuticals and Medical Device by Yuwadee Patanawong

Evaluation

2012 APEC

- ✓ Did we meet these objectives?
- ✓ Was it useful to you?
- ✓ Was the content and format right?
- ✓ What worked well?
- ✓ What could be improved?

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Culture Night

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Thanks for your Attention